



Hygroplex™ HHG

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Hygroplex HHG

Raw Material Documentation

- 1. Trade name:** Hygroplex HHG
Use: Active for cosmetics
Manufacturer: Supplier:
CLR – Chemisches Laboratorium
Dr. Kurt Richter GmbH
Sperenberger Straße 3
12277 Berlin / Germany
Tel.: +49 30 851026 – 0
Contact for information:
Sales Department

- 2. Raw Material Composition**
Chemical Name (IUPAC), Formula
Not applicable, as mixture.

Characterization

Contains mono- and disaccharides in natural combination with amino acids. Further components: hexylene glycol, urea and hexyl nicotinate. Aqueous medium.

Origin

Synthetic/plant-derived.

- 3. INCI Name**
(composition in percentages [ranges] according to FDA recommendations)

INCI Name	EU Name	Range (FDA)
Hexylene Glycol	./.	25 – 50 %
Fructose	./.	5 – 10 %
Glucose	./.	5 – 10 %
Sucrose	./.	0,1 – 1 %
Urea	./.	0,1 – 1 %



Hygroplex HHG

Raw Material Documentation

INCI Name	EU Name	Range (FDA)
Dextrin	./.	0,1 – 1 %
Alanine	./.	< 0,1 %
Glutamic Acid	./.	< 0,1 %
Aspartic Acid	./.	< 0,1 %
Hexyl Nicotinate	./.	< 0,1 %
(Water portion approx. 35 %)		

4. Registration

<i>EINECS Designation:</i>	<i>EINECS No.:</i>	<i>CAS No.:</i>
2,4-Pentanediol, 2-methyl-	203-489-0	107-41-5
D-Fructose	200-333-3	57-48-7
D-Glucose	200-075-1	50-99-7
α -D-Glucopyranoside, β -D-Fructofuranosyl	200-334-9	57-50-1
Urea	200-315-5	57-13-6
Dextrin	232-675-4	9004-53-9
L-Alanine	200-273-8	56-41-7
L-Glutamic acid	200-293-7	56-86-0
L-Aspartic acid	200-291-6	56-84-8
3-Pyridinecarboxylic acid, hexyl ester	245-767-4	23597-82-2

5. Pharmacopoeial Registration

./.

6. Manufacturing Procedure

The above-mentioned ingredients are combined following a special mixing procedure. Subsequent high-pressure filtration yields the product Hygroplex HHG.



Hygroplex HHG

Raw Material Documentation

7. Raw Material Properties

Appearance, Odour

Pale-yellow liquid with characteristic odour.

Solubility

Soluble in water in any proportion.

Recommended Use:

In emulsified, aqueous and aqueous-alcoholic moisturizing cosmetics designed for the care of dry skin. In addition, for the care of stressed/damaged hair which lacks elasticity and strength due to invasive hairdressing procedures.

8. Analytical Data

Quality Control

Refractive index n_D^{20}	1.414 – 1.416
Density 20 °C	1.050 – 1.053 g/ml
Colour value (Gardner)	0 - 4
Total nitrogen (Kjeldahl)	0.4 – 0.6 %
Glucose	5 – 8 %
Colony forming units	
Total aerobic microbial count (TAMC)	< 100/ml
Total combined yeasts/moulds count (TYMC)	< 10/ml
	in absence of non conforming organisms

9. Methods of Identification

Total of quality control data.



Hygroplex HHG

Raw Material Documentation

10. Contaminants/Reaction Intermediates occurring in the Raw Material

Contaminants	not to be expected	Concentrations	Methods
Formaldehyde	x		
Nitrosamines	x		
1,4-Dioxane	x		
Free ethylene oxide	x		
Monochloroacetic acid	x		
Dichloroacetic acid	x		
Monomers	x		
Halogenous organic compounds	x		
Polycyclic aromatic hydrocarbons	*		
Pesticides	*		
Heavy metals			
As		< 0.1 mg/kg	ICP-MS** ***
Pb		< 0.05 mg/kg	ICP- MS** ***
Cd		< 0.01 mg/kg	ICP-MS** ***
Hg		< 0.005 mg/kg	AAS Cold Vapour**
Sb		< 0.1 mg/kg	ICP-MS** ****
Allergenic substances (acc. to 2003/15/EC)	x		
Others	./.		

* no data available **spot-checked *** (EN 15763:2009)
**** (DIN EN ISO 17294-2-E29)

11. Stabilizing Additives

./.

12. Microbiology

Colony forming units (the total of aerobic, anaerobic and fungal colonies): < 100/ml. Check for absence of characteristic pathogenic germs (Aspergillus niger, Candida albicans, Staphylococcus aureus, E. coli, Pseudomonas aeruginosa) is done using a sample of 1.0 ml.



Hygroplex HHG

Raw Material Documentation

13. Physiological Safety

Acute Toxicity

LD₅₀ oral: > 9 ml/kg body weight (rat): non-toxic

Skin tolerance

An OW cream containing 10% Hygroplex HHG was applied on 50 volunteers for 48 hours in a patch test. The score concerning erythema, fissures and scaling was always zero. Hygroplex HHG can be classified as harmless as regards the possibility of skin irritation.

Skin Tolerance under Use Conditions

Product has been used in cosmetics for many years; negative effects have not been reported.

Eye irritation potential

Hygroplex HHG was diluted to 5% and 10% concentrations using sterile water and tested on the chorioallantoic membrane of the hen's egg. The 5% concentration showed an irritation index of 0.00, the 10% concentration an irritation index of 0.11. Hygroplex HHG at these concentrations was classified as "non-irritant".

Sensitization

Sensitization test/guinea-pig/Buehler: non-sensitizing

14. Information on Percutaneous Permeation

no data available

15. Genotoxicity

Bacterial Testing

no data available

Non-Bacterial Testing

no data available

16. Human Experience (as far as available)

Product has been used in cosmetics for many years; negative effects have not been reported.



Hygroplex HHG

Raw Material Documentation

17. Other Information

Chronic Toxicity

no data available

Subchronic Toxicity

no data available

Teratogenicity

no data available

Toxicokinetics

no data available

Additional Genotoxicological Tests (as far as required)

no data available

Mutagenicity

Mutagenicity test in 3 haploid strains of *Saccharomyces cerevisiae*: non-mutagenic

BSE Hazard

With the exception of honey Hygroplex HHG contains neither animal nor animal-derived raw materials and therefore does not imply any risk of BSE.

18. Potential Risks presented by UV Exposure and on Inhalation

Phototoxicity

no data available

Photosensitization

no data available

Toxicity on Inhalation

no data available



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19. Ecology

Biodegradability

Hygroplex HHG is non-toxic and its ingredients are easily biodegradable.

Acute Aquatic Toxicity

- Bacteria
 - Algae
 - Daphnia
 - Fish
- } no data available

Water Pollution Hazard Class:

1 (self-classification)

authorized by:

W. Reinhold
(Director Quality Assurance)
– valid without signature –



Hygroplex HHG

Product Specification

Characteristics

Moisturizer adapted to the "Natural Moisturizing Factors" (NMF) and containing a weakly hygroscopic substance, mono and disaccharides which are naturally combined with amino acids, urea and a factor stimulating the blood circulation.

Because of its self-preserving properties, Hygroplex HHG contains no preservative.

INCI Name	CAS No.	EINECS No.
Hexylene Glycol	107-41-5	203-489-0
Fructose	57-48-7	200-333-3
Glucose	50-99-7	200-075-1
Sucrose	57-50-1	200-334-9
Urea	57-13-6	200-315-5
Dextrin	9004-53-9	232-675-4
Alanine	56-41-7	200-273-8
Glutamic Acid	56-86-0	200-293-7
Aspartic Acid	56-84-8	200-291-6
Hexyl Nicotinate	23597-82-2	245-767-4

Analytical Data

Refractive index n_D^{20}	1.414 – 1.416
Density 20 °C	1.050 – 1.053 g/ml
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Total Nitrogen (Kjeldahl)	0.4 – 0.6 %
Glucose	5 – 8 %
Colony forming units	
Total aerobic microbial count (TAMC)	< 100/ml
Total combined yeasts/moulds count (TYMC)	< 10/ml
	in absence of non conforming organisms

Physiological Safety

Acute oral toxicity

LD₅₀ according to Litchfield and Wilcoxon in rats: 9 ml per kg of body weight.

Hygroplex HHG is hence to be designated as non-toxic.



Hygroplex HHG

Product Specification

Eye irritation potential

Hygroplex HHG was diluted to 5% and 10% concentrations using sterile water and tested on the chorioallantoic membrane of the hen's egg. The 5% concentration showed an irritation index of 0.00, the 10% concentration an irritation index of 0.11. Hygroplex HHG at these concentrations was classified as "non-irritant".

Skin tolerance

An O/W cream containing 10% Hygroplex HHG was applied on 50 volunteers for 48 hours in a patch test. The score concerning erythema, fissures and scaling was always zero. Hygroplex HHG can be classified as harmless as regards the possibility of skin irritation.

Sensitization

Hygroplex HHG (undiluted) was tested for delayed contact hypersensitivity on the skin of guinea pigs in a closed patch test. Under the given test conditions, Hygroplex HHG was found to cause no delayed contact hypersensitivity of the skin.

Mode of action

Moisturizing of the skin is a central problem in cosmetology. It is known that the stratum corneum of young skin contains "Natural Moisturizing Factors" in the correct proportion. This means that the skin can take up the water required for its satisfactory constitution, and store it in its cell tissue. Young skin is thus rich in moisture and has a good turgor. With increasing age the tissue, and particularly the skin, becomes poorer in moisture. That is to say, in this connection, "ageing" is to be equated with "drying up". In either case the turgor diminishes, the skin becomes rough and chapped (and finally withered and wrinkled). An inadequate moisturization of the skin is, however, not only and not always caused by ageing. External influences can also be responsible, for example frequent and extended contact with water, especially in conjunction with detergents. The natural moisturizing factors (hydrophilic and weakly hygroscopic substances) are water-soluble, and can therefore be dissolved out of the cell complex by water and polar solvents, and be lost to the skin. Since the decrease in natural moisturizing factors caused by ageing and environmental factors cannot be prevented, the cosmetic aim must be to supply the skin with active substances which have the property of restoring its water-binding capacity to a normal physiological level.

Hygroplex HHG has been developed on the basis of this research into natural moisturizing factors. This active agent can be designated as a "physiological" skin moisturizer. Its composition is similar to that of the natural moisturizing factors and thus protects the skin from



Hygroplex HHG

Product Specification

loss of moisture or replaces the lost factors. In contrast to strongly hygroscopic substances such as glycerin, Hygroplex HHG does not dehydrate the skin when there is low atmospheric humidity. Hygroplex HHG can take up just as much water as the skin (same water-binding capacity); it is thus adapted to the physiological functions of the skin. Hygroplex HHG contains a weakly hyperaemizing substance; it thereby supports the local blood flow, which is of importance for the hydration.

Hygroplex HHG yields the best skin moisturizing effect when incorporated at 5% into *O/W* creams. In *W/O* creams Hygroplex HHG, used at the same concentration, produces a smaller hydration effect. It is therefore advisable to use a higher concentration level, i.e. up to 10%, in *W/O* type creams. It can be concluded that Hygroplex HHG as a "water-soluble" active agent achieves a better effect from the outer phase of *O/W* creams than from *W/O* creams in which it is included in the inner phase.

Hygroplex HHG increases the moisture content of the skin, with a resultant improved turgor. This effect is documented by clinical tests.

Furthermore, comprehensive studies were conducted to assess the effect of Hygroplex HHG on human hair. The studies showed that aqueous-alcoholic lotions containing 1% Hygroplex HHG produced a remarkable regenerating effect on the hair shaft. In addition, the superficial layers of the hair were found to contain an increased amount of free water, which produced a distinct improvement of the mechanical properties of the hair.

Application

As a skin moisturizer adapted to the "Natural Moisturizing Factors", Hygroplex HHG is most suitable for application to "low-moisture" skin. That is skin which has dried up from aging or prematurely by external influences, and thus becomes rough and chapped (and finally withered and wrinkled). Hygroplex HHG is also designed for stressed hair which lacks elasticity and strength due to hairdressing procedures.

It can be used in emulsified, aqueous and aqueous-alcoholic skin moisturizing and hair cosmetics.

Dosage

Skin care preparations: 2.0 - 5.0%

Hair care preparations: approx. 1%



Hygroplex HHG

Product Specification

Appearance / Odor

Light-yellow, aqueous solution. Weak specific odor.

Solubility

Soluble in water and water-alcohol mixtures with an alcohol concentration not exceeding 60% v/v.

Processing

Hygroplex HHG is relatively thermostable and may be heated briefly to the temperatures required for the manufacture of emulsified preparations. In the manufacture of emulsified preparations Hygroplex HHG is dissolved in the water phase.

In the manufacture of aqueous-alcoholic preparations Hygroplex HHG is added to the alcohol-water mixture.

Hygroplex HHG does not affect the color of cosmetics.

The odor of Hygroplex HHG can be masked in cosmetics by perfume oils. Best suited for this purpose are rose-type fragrances.

Storage

At cellar to room temperature (15 - 25 °C), in well closed containers, protected from light.

Hygroplex HHG should not be stored for longer than 1 year before processing.

Packing

Available pack sizes: 1 kg, 5 kg, 25 kg

Sample size: 50 g

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Hygroplex HHG
Revision date : 17.06.2019
Print date : 23.06.2021

Version (Revision) : 4.0.1 (4.0.0)

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

1.1 Product identifier

Hygroplex HHG (244)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

PC 39 - Cosmetics, personal care products

Uses advised against

No information available.

Remark

The product is intended for professional use.

1.3 Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor)

CLR Chemisches Laboratorium
Dr. Kurt Richter GmbH

Street : Sperenberger Strasse 3

Postal code/city : D-12277 Berlin

Telephone : +49 30 851026-0

Telefax : +49 30 851026-85

Information contact : Info@clr-berlin.com

1.4 Emergency telephone number

+49 30 851026-0 (Available at: Mon.-Thu. 8.00 am - 4.30 pm; Fri. 8.00 am - 3.30 pm)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

Eye Irrit. 2 ; H319 - Serious eye damage/eye irritation : Category 2 ; Causes serious eye irritation.

Skin Irrit. 2 ; H315 - Skin corrosion/irritation : Category 2 ; Causes skin irritation.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms



Exclamation mark (GHS07)

Signal word

Warning

Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements

P264 Wash ... thoroughly after handling.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Hygroplex HHG
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Version (Revision) : 4.0.1 (4.0.0)

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P321 Specific treatment (see ... on this label).
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description

Contains mono- and disaccharides in natural combination with amino acids; in addition, hexylene glycol, urea and hexyl nicotinate in aqueous medium.

Hazardous ingredients

2-METHYLPENTANE-2,4-DIOL ; REACH No. : 01-2119539582-35 ; EC No. : 203-489-0; CAS No. : 107-41-5

Weight fraction : $\geq 40 - < 45$ %

Classification 1272/2008 [CLP] : Skin Irrit. 2 ; H315 Eye Irrit. 2 ; H319

This mixture contains the following substances of very high concern (SVHC) which are included in the Candidate List according to Article 59 of REACH

None

This mixture contains the following substances of very high concern (SVHC) which are subject to authorisation according to Annex XIV of REACH

None

Additional information

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

Following inhalation

Provide fresh air.

In case of skin contact

Water and soap

After eye contact

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

None

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Hygroplex HHG
Revision date : 17.06.2019
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Version (Revision) : 4.0.1 (4.0.0)

Water Carbon dioxide (CO₂) Foam

Unsuitable extinguishing media

None

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

The product itself does not burn.

5.3 Advice for firefighters

Do not inhale explosion and combustion gases.

5.4 Additional information

Do not allow run-off from fire-fighting to enter drains or water courses.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

No special measures are necessary.

6.2 Environmental precautions

Do not allow to enter into surface water or drains.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

6.4 Reference to other sections

None

SECTION 7: Handling and storage

7.1 Precautions for safe handling

None

7.2 Conditions for safe storage, including any incompatibilities

Hints on joint storage

Storage class (TRGS 510) : 10

Further information on storage conditions

Protect against : UV-radiation/sunlight Frost

Storage temperature : 15 - 25 °C (59 - 77 °F)

7.3 Specific end use(s)

None

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

DNEL-/PNEC-values

DNEL/DMEL

No substance related limit value derivable.

PNEC

No substance related limit value derivable.

8.2 Exposure controls

Personal protection equipment

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



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Version (Revision) : 4.0.1 (4.0.0)



Eye/face protection

Suitable eye protection

Eye glasses with side protection

Skin protection

Hand protection

Suitable gloves type : Disposable gloves.

Suitable material : PE (polyethylene) NR (natural rubber, natural latex) NBR (Nitrile rubber)

Thickness of the glove material : > 0.1 mm

Respiratory protection

Usually no personal respirative protection necessary.

General information

When using do not eat, drink, smoke, sniff. Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state : Liquid

Colour : light yellow

Odour

characteristic

Safety characteristics

Physical state :			Liquid
Initial boiling point and boiling range :	(1013 hPa)	approx.	100 °C
Flash point :		>	100 °C
Vapour pressure :	(50 °C)		No data available
Density :	(20 °C)		1,05 - 1,053 g/cm ³
Solvent separation test :	(20 °C)		No data available
pH :	(20 °C / 100 g/l)		3,8 - 5
Viscosity :	(20 °C)	approx.	20 mPa*s

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

No information available.

10.2 Chemical stability

No information available.

10.3 Possibility of hazardous reactions

No information available.

10.4 Conditions to avoid

No information available.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Hygroplex HHG
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Version (Revision) : 4.0.1 (4.0.0)

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Acute oral toxicity

Parameter : LD50
Exposure route : Oral
Species : Rat
Effective dose : > 9 mL/kg
Method : OECD 401

Corrosion

Skin corrosion/irritation

Parameter : Skin corrosion/irritation
Species : Human
Exposure time : 48 h
Result : Not irritant
Method : Patch test (10% in o/w-cream)

Serious eye damage/eye irritation

Parameter : Serious eye damage/eye irritation
Species : hen's egg
Result : Not irritant
Method : HET-CAM (5% solution)
Parameter : Serious eye damage/eye irritation
Species : hen's egg
Result : Not irritant
Method : HET-CAM (10% solution)

Assessment/classification

The product is not irritant, if used at the recommended concentrations

Respiratory or skin sensitisation

Skin sensitisation

Parameter : Sensitisation
Species : Guinea pig
Result : Not sensitizing
Method : OECD 406

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

The ingredients in this mixture do not meet the criteria for classification as CMR category 1A or 1B according to CLP.

SECTION 12: Ecological information

12.1 Toxicity

No information available.

12.2 Persistence and degradability

Biodegradation

Biodegradable.

12.3 Bioaccumulative potential

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



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Version (Revision) : 4.0.1 (4.0.0)

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

12.6 Other adverse effects

No information available.

12.7 Additional ecotoxicological information

None

SECTION 13: Disposal considerations

13.1 Waste treatment methods

No information available.

SECTION 14: Transport information

14.1 UN number

No dangerous good in sense of these transport regulations.

14.2 UN proper shipping name

No dangerous good in sense of these transport regulations.

14.3 Transport hazard class(es)

Land transport (ADR/RID)

No dangerous good in sense of these transport regulations.

Class(es) : -

Sea transport (IMDG)

No dangerous good in sense of these transport regulations.

Class(es) : -

Air transport (ICAO-TI / IATA-DGR)

No dangerous good in sense of these transport regulations.

Class(es) : -

14.4 Packing group

No dangerous good in sense of these transport regulations.

14.5 Environmental hazards

No dangerous good in sense of these transport regulations.

14.6 Special precautions for user

None

SECTION 15: Regulatory information

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

EU legislation

Authorisations and/or restrictions on use

Restrictions on use

Use restriction according to REACH annex XVII, no. : 3

National regulations

Water hazard class (WGK)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Hygroplex HHG
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Version (Revision) : 4.0.1 (4.0.0)

Class : 1 (Slightly hazardous to water) Classification according to AwSV

15.2 Chemical safety assessment

No information available.

SECTION 16: Other information

16.1 Indication of changes

15. Restrictions on use · 15. Water hazard class (WGK)

16.2 Abbreviations and acronyms

None

16.3 Key literature references and sources for data

None

16.4 Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

No information available.

16.5 Relevant H- and EUH-phrases (Number and full text)

H315 Causes skin irritation.
H319 Causes serious eye irritation.

16.6 Training advice

None

16.7 Additional information

None

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.