Cosmetic Product Safety Report

according to chapter III, article 10 of
Regulation (EC) No. 1223/2009 of the
European Parliament and of the Council

Product name:	Locked and Loaded
Product type:	Bonder
Formula:	2761GDHR
Company:	Sinful Lashes 15617-A Ventura Blvd, Encino, CA 91436
Version:	1.0
Date:	07/2018

Cosmetic Product Safety Information

Quantitative and qualitative composition of the cosmetic product

Formula with INCI names

INCI name	Concentration	CAS #	EINECS/ ELINCS #	Intended Function
Alcohol denat	0,7-1	n.a.	n.a.	Solvent
Allantoin	0,01-0,02	97-59-6	202-592-8	Skin Conditioning
Aqua	up to 100%	7732-18-5	231-791-2	Solvent
Benzoic Acid	0,01-0,02	65-85-0	200-618-2	Preservative
Citrus Limon Fruit Extract	0,03-0,06	92346-89-9	296-174-2	active
Cucumis Sativus Fruit Water	0,05-0,1	89998-01-6	789-738-4	Skin Conditioning
Dehydroacetic Acid	0,01-0,02	520-45-6	208-293-9	Preservative
Ethylhexylglycerin	0,005-0,01	70445-33-0	408-080-2	Additive
Glycerin	0,5-2	56-81-5	200-289-5	solvent
Glycine Soja Seed Extract	0,027-0,054	n.a.	n.a.	Skin Conditioning
Hamamelis Virginana Leaf Water	0,02-0,045	84696-19-5	283-637-9	Skin Conditioning
Lactic Acid	0,00054-0,0054	50-21-5	200-018-0	pH Adjuster
Panthenol	0,05-0,09	81-13-0	201-327-3	Skin Conditioning
Parfum	0,02-0,04	n.a.	n.a.	Perfuming
Phenoxyethanol	0,1-0,2	122-99-6	204-589-7	Preservative
Polysorbate 20	0,3-0,8	9005-64-5	n.a.	Emulsifying
Potassium Sorbate	0,005-0,009	24634-61-5	246-376-1	Preservative
Propylene Glycol	0,4-0,54	57-55-6	200-338-0	Solvent
Sodium Benzoate	0,005-0,009	532-32-1	208-534-8	Preservative
Sodium Chloride	0,5-1	7647-14-5	n.a.	Additive

Physical/chemical characteristics and stability of the cosmetic product

Product specification
The product is developed for daily face care
The main active ingredients are Hamamelis Virginiana Leaf Water, Panthenol, Cucumis Sativus Fruit Water, Citrus Limon Fruit Extract and Glycine Soja Seed Extract.

Product type
Skin care product: Leave-on-product

Emulsion type
liquid

Ph value
n.a.

Appearance
Slightly yellow liquid

Microbiological quality

Microbial Contamination/Specification
Microbial Contamination/Specification
A Challenge Test according to the European Pharmacopoeia 2011:5.1.3 was rouled out by Dr. Straetmans GmbH. Test result After addition of pathogenic microorganism there was a completely reduction of the germs and the product fulfill Criteria A of the Ph.EUR. The sample was germfree before starting the test

Stability/Shelf Life
Storage test over a period of 6 months at room temperature, 5 ° C and 40° C was rouled out
Test result: No visible changements of the product

Impurities, traces information about the packaging material

The packaging material is usable as packaging for cosmetic products according European regulatins and German laws

Exposure of the cosmetic product

The site(s) of application
face & lash care

The surface area(s) of application
Circa 565 cm_2

The amount of product applied
The maximum amount: 1,0 g

The duration and frequency of use
2 times per day

The normal and reasonably foreseeable exposure route(s)
Application on the face & lash

The target (or exposed) population(s). Potential exposure of
Adults

Foreseeable use
Contact with eyes is possible, if the product will be applicate on the eye area

Calculation of Exposure
Parameter:
Default of human body weight: 60-70 kg
Route of exposure: dermal
Kind of exposure: rinse-off Product
Retention factor: R: 1,0
Skin surface area: 565 cm_2
Typical amount per application: 1,ßg
Frequency of application of the finished product: 2/day
The total daily amount is: 2,0 g/day

Exposure of the substances

Dermal absorption reported as a percentage of the amount of substance applied:
The calculation of the SED will be as follows:
SED= A (G/day) x 1000 mg/g x C (%)/100 x D_{Ap} (%)/100
SED (mg/kg bw/day)=Systemic Exposure Dosage
A (g/day)= Amount of the cosmetic product applied daily
C(%)= the concentration of the ingredient under study in the finished cosmetic product on the application site
Dap (%)= Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real life conditions
D in leave-on-products: 100 % (worst case)
D in rinse-off-products: 1 %
60 kg = default human body weight

Toxicological profile of the substance

Trade Name: VE-Wasser 80°C
INCI: Aqua
Specification of the raw material:
Microbiological specification:
Total plate count: < 100 KBE/ml
Fullfill the requirements of the TrinkwV.

INCI: Hamamelis Virginiana Leaf Water
Acute orale toxicity: LD50 mouse oral: 4610 mg//kg [9]
Subchronic toxicity: NOAEL: 2920 mg/kg/bw/90d [9]
Percutanous permeation: no data available
Dermale Irritation: non irritating [9]
Mucosal/Eye Irritation: non irritating [9]
Sensitization Potential: no sensitization potential [9]
Mutagenicity: no mutagenic potential [9]

INCI: Alcohol denat.
Acute oral toxicity: TDLo woman oral: 1200 mg/kg [9]
Subchronic toxicity: NOAEL: 19 g/ kg/bw/90d [9]
Percutanous permeation: no data available
Dermal Irritation: skin rabbit: 400 mg open MLD [9]
Mucosal/Eye Irritation: eye rabbit: 500mg SEV [9]
Sensitization Potential: no sensitization known [9]
Mutagenicity: no data available

Specification of the raw material:
Total plate count: <100 KBE/g
Yeast & Molds: < 10 KBE/g
Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, E. Coli: not detectable

INCI: Sodium Chloride

Identity	given by each specific assay	corresponds
Appearance of solution	clear and colorless	corresponds
pH (at 20-25°C)	release specification 4.5-7.0	5.6
Clarity and degree of opalescence"	< 3 NTU	0
Particulate contamination	> 10µm max. 25 particles / ml	0
	> 25µm max. 3 particles / ml"	0
Sterility	sterile	corresponds
Bacterial Endotoxins	< 0,25IU/ml	corresponds
Sodium	146,3-161,7mmol/l	149,8
Chloride	146,3-161,7mmol/l	153,2

INCI: Allantoin
Acute oral toxicity: LD 50 rat oral: >5000 mg/kg [9]
Subchronic toxicity: no data available
Percutaneous permeation: no data available
Dermal Irritation: non irritant [Eggensperger]
Mucosal/Eye Irritation: non irritant (Draize) [Eggensperger]
Sensitization Potential: no data available
Mutagenicity: no data available
CIR-Compendium: Safe up to 2%

INCI: Panthenol
Acute oral toxicity: LD 50 rat oral: 15000mg/kg [9]
Subchronic toxicity: no data availabe
Percutanous permeation: no data available
Mucosal/Eye Irritation: 500µg MLD [9]
Skin Irriation: rabbit 500mg/4H MLD
Sensitization Potential: no data available
Mutagenicity:: no data available
CIR Compendium: Safe up to 6 %

INCI: Cucumis Sativus Fruit Water
CIR Compendium: Safe up to 3%

INCI: Potassium Sorbate
In the Annex 6 I, No. 4 are the following restrictions:
Maximum authorized concentration: 0,6% (acid)

INCI: Sodium Benzoate
In the Annex 6 A, No. 1 are the following restrictions:
Maximum authorized concentration: 0,5% leave-on-products

Specification of the raw material:
Total plate count: <100 KBE/g
Yeast & Molds: < 10 KBE/g
Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, E. Coli: not detectable

INCI: Propylene Glycol
Acute oral toxicity: LD 50 rat oral: 20g/kg [9]
Subchronic toxicity: NOAEL: 425 mg/kg/bw/90d [9]
Percutaneous permeation: no data available
Dermal Irritation: 500mg/7DMLD [9]
Mucosal/Eye Irritation: 100 mg MLD [9]
Sensitization Potential: no data available
Mutagenicity: no data available

INCI: Glycine Soja Seed Extract
Acute oral toxicity: LD 50 mouse oral: 22100 mg/kg [9]
Subchronic toxicity: TDLo mouse oral: 168g/kg/26 w [9]
Percutanous permeation: no data available
Mucosal/Eye Irritation: no data available
Sensitization Potential: no data available
Mutagenicity:: no data available
CIR-Compendium: Safe

INCI: Potassium Sorbate
In the Annex 6 I, No. 4 are the following restrictions:
Maximum authorized concentration: 0,6% (acid)

INCI: Sodium Benzoate:
In the Annex 6 A, No. 1 are the following restrictions:
Maximum authorized concentration: 0,5% leave-on-products

INCI: Lactic Acid
Subchronic toxicity: no data available
Percutanous permeation: no data available
Dermale Irritation: skin rabbit: 100mg/24 H MOD
Mucosal/Eye Irritation: eye rabbit 750 µg/SEV [9]
Sensitization Potential: no data available
Mutagenicity: no data available
JECFA: ADI not limited in food
CIR-Compendium: Safe < 10%

INCI: Alcohol denat.
Acute oral toxicity: TDLo woman oral: 1200 mg/kg [9]
Subchronic toxicity: NOAEL: 19 g/ kg/bw/90d [9]
Percutanous permeation: no data available
Dermal Irritation: skin rabbit: 400 mg open MLD [9]
Mucosal/Eye Irritation: eye rabbit: 500mg SEV [9]
Sensitization Potential: no sensitization known [9]
Mutagenicity: no data available
The Alcohol is denaturated with: 0,024%Diethylphtalate

INCI: Diethyl Phthalate
Subchronic toxicity: no data available
Percutanous permeation: no data available
Dermale Irritation: no data available
Mucosal/Eye Irritation: no data available
Sensitization Potential: no data available
Mutagenicity: no data available
JECFA: ADI not limited in food
CIR-Compendium: Safe up to 99%

INCI: Polysorbate-20
Acute oral toxicity: LD 50 mouse oral: > 33g/kg [9]
Subchronic toxicity: no data available
Percutanous permeation: no data available
Dermal Irritation: non irritating to the skin [9]
Mucosal/Eye Irritation: no data available
Sensitization Potential: no data available
Mutagenicity:: no data available
CIR Compendium: Safe up to > 50%

INCI: Parfum
See IFRA Conformity Certificate
The product contains the following allergenic substances:
Contains Benzyl Alcohol: Annex III/I No.:34 Concentration: 0,000006%
Contains Benzyl Benzoate: Annex III/I, No.:85 Concentration: 0,000003%
Contains Benzyl Salicylate: Annex III/I , No.:75 Concentration: 0,000004%
Contains Cinnamyl Alcohol: Annex III/II No.:69 Concentration: 0,000004%
Declaration is required if the concentration is higher than 0,01% in rinse-off product or more than 0,001% in leave-on- products.
The perfume contains 0,000058 Methyl Benzoate and 0,000014% BHT
In the Annex 6 A, No. 1 are the following restriction for Methyl Benzoate
Maximum authorized concentration: 0,5% leave-on-products.
Due to the low concentration, it`s not necessary to indicate them on the label.

INCI: Phenoxyethanol
In the Annex 6 I, No. 29 are the following restrictions:
Maximum authorized concentration: 1,0%

INCI: Benzoic Acid:
In the Annex 6 A, No. 1 are the following restrictions:
Maximum authorized concentration: 0,5% leave-on-products

INCI: Dehydroacetic Acid
In the Annex 6 I, No. 13 are the following restrictions:
Maximum authorized concentration: 0,6% (acid)
Prohibited in aerosol dispensers

INCI: Ethylhexylglycerin
Subchronic toxicity: NOAEL: 96mg/kg/bw/90d [9]
Percutaneous permeation: no data available
Dermal Irritation: Skin rabbit:500mg/24H MLD [9]
Mucosal/Eye Irritation: Eye rabbit: 126 mg MLD [9]
Sensitization Potential: no data available
Mutagenicity: no data available
Specification of the raw material:
Ethylhexylglycerin is stabilized with Tocopherol

Lemon, INCI: Aqua, Glycerin, Citrus Limon Fruit Extract, Sodium Benzoate, Potassium Sorbate

FIRST AID MEASURES
Description of first aid measures
In case of:

Skin Contact:	Remove clothing contaminated with the product immediately. Wash with soap and water.
Eye Contact:	Rinse away thoroughly with water at least for 15minutes.
Ingestion:	If large amount swallowed or symptoms develop obtain medical attention.
Inhalation:	Remove victim to fresh air.

Most important symptoms and effects, both acute and delayed
None known

Indication of any immediate medical attention and special treatment needed
No data available

FIREFIGHTING MEASURES

Extinguishing media

Extinguishing Media:
Dry chemical
Alcohol type foam
Water spray, CO2

Special hazards arising from the substance or mixture
None known

Advice for firefighters
Use air supplied breathing equipment for enclosed areas. Cool exposed containers with water spray.
Avoid breathing vapor and fumes.

ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Do not try to clean up the leak without the proper protective equipment.

Environmental precautions
Avoid liquid to enter sewer/public waters
Absorb the small overflows with inert solids
Notify environmental authorities in case of large leaks.

Methods and material for containment and cleaning up

Reference to other sections
No data available

HANDLING AND STORAGE

Precautions for safe handling
Handle in accordance with good industrial hygiene and safety practices.

Conditions for safe storage, including any incompatibilities
Store protected from light and humidity in tightly closed vessels at room temperature.

Specific end uses
No data available

EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters
No data available

Exposure controls
Respiratory protection: Not needed
Body protection: Not needed
Eye protection: Not needed

Information on basic physical and chemical properties

* These physical data are typical values and should not be construed as a guaranteed analysis of any specific lot or as specification items

Form: Liquid
Colour: Yellow
Odour: Characteristic.
Odour threshold: No data available
pH: <7.5, within the established safety limits: 2 - 11.5 (according to EC 440/2008 part B.4, OCDE nº 404).
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: 105 ºC
Evaporation rate: No data available
Flammability (solid, gas): No data available
Upper/lower flammability or explosive limits: No data available
Vapour pressure: No data available
Vapour density: No data available
Relative density: >1.000
Solubility: Solubility in water: Soluble
Partition coefficient: n-octanol/water: No data available
Auto-ignition temperature: 400 ºC
Decomposition temperature: No data available
Viscosity: No data available
Explosive properties: No data available
Oxidising properties: No data available

STABILITY AND REACTIVITY
Reactivity
No data available

Chemical stability
Stable under usual conditions

Possibility of hazardous reactions
Will not occur.

Conditions to avoid
Keep sources of ignition at a distance.

Incompatible materials
No data available

Hazardous decomposition products
Will not occur.

Information on toxicological effects
Acute toxicity: No toxic
Skin corrosion/irritation: No irritant
Eye Irritation: No irritant
Sensitisation: No data available
Mutagenicity: No mutagenic
Carcinogenicity: No carcinogenic
Toxicity for reproduction: No toxic
Repeated dose toxicity: No toxic

ECOLOGICAL INFORMATION

Toxicity
Glycerin: Multiplication inhibition test in algae (Microcystis aeruginosa) and protozoa (Entosiphon sulcatum): Toxicity threshold = 2900 mg/l and 3200 mg/l (HSDB no. 492, revision: 20050624).
Glycerin (HSDB no. 492, revision: 20050624): LC50 goldfish > 5000 mg/l/24h.

Persistence and degradability
Glycerin (HSDB no. 492, revision: 20050624): Activated sludge test: 220 mg/l resulted in a COD of 97%; Test in a 5 days: BOD = 82%. Glycerin is considered an easily degradable substance.

Bioaccumulative potential
No data available

Mobility in soil
No data available

Results of PBT and vPvB assessment
No data available

Other adverse effects
No data available

DISPOSAL CONSIDERATIONS

Waste treatment methods
The product or water contaminated must not be considered as dangerous residues. Eliminate according to the existing regulations.

TRANSPORT INFORMATION
Non-dangerous product for the transport
14.1. UN number
14.2. UN proper shipping name
14.3. Transport hazard class(es)
14.4. Packing group
14.5. Environmental hazards
14.6. Special precautions for user
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture.
No data available

Chemical safety assessment
No data available

Calculation of exposure

The MOS should be at least 100 to declare a substance safe for use.
The margin of safety is defined as the ratio between the maximum dose tolerated without unwanted effects (NOEL) and the systemically absorbed dose both expressed as mg/kg body weight.
Margin of Safety (MOS) = NO(A)EL : SED
The systemically absorbed dose (in mg/kg body eight) is calculated from the exposition dose (in mg) divided by an "average user body weight" of 60 kg.
In accordance with the SCC the NO(A)EL used for the calculation of the MOS refers to the subacute/chronic toxicity effects wherever the respective data exist.

Undesirable effects and serious undesirable effects

No undesirable effects and serious undesirable effects will be expected

Information on the cosmetic product

Statistic of complaints:
There are no complaints

Literature

1. Beck'sche Textsammlung Lebensmittelrecht, Kosmetik Verordnung

2. Notes of guidance for testing of cosmetic ingredients for their safety evaluation, SCCNFP/0321/00 Final

3. H.P. Fiedler, Lexikon der Hilfsstoffe für Pharmazie, Kosmetik und angrenzende Gebiete, Editio Cantor Verlag Aulendorf, 4. Auflage

4. Hagers Handbuch der Pharmazeutischen Praxis, 5. Auflage,1990

5. Römpp Chemie Lexikon, 9. Auflage

6. M. Fey, J. Otte: Wörterbuch der Kosmetik, 3. Auflage, 1991

7. Blaue Liste, 2. Auflage, 1993

8. W. Umbach: Kosmetik, Thieme Verlag

9. Data Base: RTECS, Toxline, Toxcas

10. Material Safety Data Sheets

11. Technical Data Sheets