Safety Data Sheet

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

Permanent make-up pigments Etalon Mix Series Light

version number: GHS 1.1 date of compilation: 2023-12-08

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

1.1 Product identifier

Identifier	**Permanent make-up pigments Etalon Mix Series Light**
Registration number (REACH)	Not relevant (Mixture)
Trade name	Lips #1 Europe Lips #2 Asia Lips #3 Africa Lips #4 America Lips #5 Australia Lips #6 Atlantis Areola #1 Areola #2 Areola #3 Areola #4 Areola #5 Areola #6

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

Relevant identified uses	Mixture for use in tattoos or permanent make-up
Uses advised against	Not determined

1.3 Details of the supplier of the safety data sheet

Stich Trade Sp z o.o.
Grzybowska 87
00-844 Warszawa
Poland

Telephone: +48731263348
e-mail: stich.trade@gmail.com

1.4 Emergency telephone number

Emergency phone number	112 / 998 / 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

2.2 Label elements

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

Signal word	Not required
Pictograms	Not required

Supplemental hazard information

EUH211	Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.

2.3 Other hazards

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.1 Substances

not relevant (mixture)

3.2 Mixtures

A mixture of unclassified pigments. The set of used pigments varies depending on the color of the product.

Name of substance	Identifier	Wt%	Classification acc. to GHS	Notes
1,2-Propanediol	CAS No 57-55-6 EC No 200-338-0	12 – 25		OEL
Titanium dioxide	CAS No 13463-67-7 EC No 236-675-5 Index No 022-006-00-2	10 – 15	Carc. 2 / H351	10(a) GHS-HC V W
Silicon dioxide	CAS No 7631-86-9 EC No 231-545-4	5 – 10		OEL
Carbon Black	CAS No 1333-86-4 EC No 215-609-9	≤ 1		OEL

Notes

10(a): Classification as a carcinogen by inhalation: Mixtures in powder form containing 1 % or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤10 µm.

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/2008/EC, Annex VI)

OEL: Substance with the national occupational exposure limit values

V: If the substance is to be placed on the market as fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1) or particles of the substance fulfilling the WHO fibre criteria or as particles with modified surface chemistry, their hazardous properties must be evaluated in accordance with Title II of Regulation (EC) No. 1272/2008, to assess whether a higher category (Carc. 1B or 1A) and/or additional routes of exposure (oral or dermal) should be applied.

W: It has been observed that the carcinogenic hazard of this substance arises when respirable dust is inhaled in quantities leading to significant impairment of particle clearance mechanisms in the lung.

For full text of abbreviations: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

The product can be considered not dangerous for humans and the environment, in the correct operating. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

Remove person to fresh air and keep comfortable for breathing. If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions.

Following skin contact

Wash with plenty of soap and water. If skin irritation persists, call a physician.

Following eye contact

Immediately flush with a large amount of water for at least 15 minutes, including under the eyelids. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Following ingestion

Rinse mouth immediately and drink plenty of water. Activated carbon and saline laxative may be used as soon as it is available. Contact your doctor if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

Description of known symptoms following exposure, if relevant - see section 11.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray. Foam. Dry extinguishing powder. BC-powder. Carbon dioxide (CO2).

Unsuitable extinguishing media

Water jet.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

This material will not burn but contains combustible ingredients. Hazardous combustion products: carbon monoxide (CO), carbon dioxide (CO2).

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Fire fighting crew should be adequately trained and equipped with self-contained breathing apparatus and full protective clothing. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Stop the leak if possible and safe to do so (seal, close the liquid isolation valve, put the leaking or damaged container to emergency container). Eliminate all sources of ignition.

For non-emergency personnel

Remove persons to safety. Ventilate affected area. Contact emergency services where appropriate.

For emergency responders

Wear suitable personal protection.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to clean up a spill

In case of small spills: wipe up with absorbent material (e.g. cloth, fleece), rinse with water.
In case of large spills: Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder). Use mechanical handling equipment.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Read label before use. Comply with the current legislation concerning the prevention of industrial risks. Control spills and residues, destroying them with safe methods (section 6). Containers which were opened must be carefully closed and kept upright to prevent leakage.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed and dry at least 1 m away from heaters in conditions that exclude aggressive environments. Recommended storage temperature: from 5 to 28 °C. The shelf life of products in the manufacturer's packaging is no more than 12 months.Products after opening the package should be stored for no more than 3 months.

Packaging compatibilities

Suitable packaging: transparent high-pressure polyethylene bottles; transparent bottles for infusion products; vials and other containers suitable for packaging medical preparations, perfumery and cosmetic products with tightly closing caps.

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Ceiling-C [ppm]	Ceiling-C [mg/m³]	Notation	Source
IE	iron(III) oxide (rouge)	1309-37-1	OELV		5		10			Fe, fume	S.I. No. 619 of 2001
IE	rouge	1309-37-1	OELV		10					i	S.I. No. 619 of 2001
IE	rouge	1309-37-1	OELV		4					r	S.I. No. 619 of 2001
IE	carbon black	1333-86-4	OELV		3					i	S.I. No. 619 of 2001
IE	titanium dioxide	13463-67-7	OELV		10					i	S.I. No. 619 of 2001
IE	titanium dioxide	13463-67-7	OELV		4					r	S.I. No. 619 of 2001

Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Ceiling-C [ppm]	Ceiling-C [mg/m³]	Notation	Source
IE	propane-1,2-diol	57-55-6	OELV		10					particle	S.I. No. 619 of 2001
IE	propane-1,2-diol	57-55-6	OELV	150	470					vp	S.I. No. 619 of 2001
IE	silica, amorphous	7631-86-9	OELV		6					i	S.I. No. 619 of 2001
IE	silica, amorphous	7631-86-9	OELV		2.4					r	S.I. No. 619 of 2001

Notation

Ceiling-C	Ceiling value is a limit value above which exposure should not occur
Fe	Calculated as Fe (iron)
fume	As fume
i	Inhalable fraction
particle	As airborne particles
r	Respirable fraction
STEL	Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)
TWA	Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)
vp	As vapours and particulates

Relevant PNECs of components of the mixture

Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
1,2-Propanediol	57-55-6	PNEC	260 mg/l	aquatic organisms	freshwater	short-term (single instance)
1,2-Propanediol	57-55-6	PNEC	26 mg/l	aquatic organisms	marine water	short-term (single instance)
1,2-Propanediol	57-55-6	PNEC	20,000 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
1,2-Propanediol	57-55-6	PNEC	572 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
1,2-Propanediol	57-55-6	PNEC	57.2 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
1,2-Propanediol	57-55-6	PNEC	50 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Appropriate engineering controls

Local and general ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

Protective coat.

Hand protection

Wear protective gloves.

Other protection measures

Wash hands thoroughly after handling.

Respiratory protection

Not required under normal conditions of use.

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
	Homogeneous liquid pasty mass
Colour	Various colours
Odour	Odourless
Melting point/freezing point	Not determined
Boiling point or initial boiling point and boiling range	Not determined
Flammability	non-combustible
Lower and upper explosion limit	Not determined
Flash point	Not determined
Auto-ignition temperature	Not determined
Decomposition temperature	Not relevant
PH (value)	Not determined
Kinematic viscosity	Not determined
Solubility(ies)	Not determined

Partition coefficient

Partition coefficient n-octanol/water (log value)	This information is not available

Vapour pressure	Not determined

Density and/or relative density

Density	Not determined
Relative vapour density	information on this property is not available

Particle characteristics	Not relevant - Liquid

9.2 Other information

Information with regard to physical hazard classes	Not relevant
Other safety characteristics	There is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions. Reacts with oxidants and reductants.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

10.5 Incompatible materials

acids, oxidisers, reducing agents, combustible materials

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

Acute toxicity

Not classified as a mixture with acute toxicity.

Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
1,2-Propanediol	57-55-6	oral	LD50	22,000 $^{mg}/_{kg}$	rat
1,2-Propanediol	57-55-6	dermal	LD50	>2,000 $^{mg}/_{kg}$	rabbit

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic. The classification as carcinogenic due to the presence of titanium dioxide applies only to powdered mixtures where the formation of respirable dust is possible.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

Abdominal pain.

If in eyes

Irritation. Tearing. Conjunctival suffusion.

If inhaled

Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

If on skin

May cause irritation, redness, allergic skin reaction.

11.2 Information on other hazards

There is no additional information.

Endocrine disrupting properties

The mixture does not contain substance(s) with an endocrine disrupting potential.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute)

Test data are not available for the complete mixture.

Aquatic toxicity (acute) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
1,2-Propanediol	57-55-6	LC50	40,613 $^{mg}/_{l}$	fish	96 h
1,2-Propanediol	57-55-6	ErC50	34,100 $^{mg}/_{l}$	algae	48 h

Aquatic toxicity (chronic)

Test data are not available for the complete mixture.

12.2 Persistence and degradability

Biodegradation

The relevant substances of the mixture are readily biodegradable.

Degradability of components of the mixture

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
1,2-Propanediol	57-55-6	oxygen depletion	106.8 %	28 d		ECHA
1,2-Propanediol	57-55-6	carbon dioxide generation	81.7 %	28 d		ECHA
1,2-Propanediol	57-55-6	DOC removal	98.3 %	28 d		ECHA

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste should be recovered or disposed of in authorized incineration plants or waste facilities in accordance with applicable regulations.

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

14.1	**UN number or ID number**	Not subject to transport regulations
14.2	**UN proper shipping name**	Not relevant
14.3	**Transport hazard class(es)**	None
14.4	**Packing group**	Not assigned
14.5	**Environmental hazards**	Non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user

There is no additional information.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

Information for each of the UN Model Regulations

International Maritime Dangerous Goods Code (IMDG)Additional information

Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR)Additional information

Not subject to ICAO-IATA.

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

None of the ingredients is on the list of prohibited pigments in accordance with Commission Regulation (EU) 2020/2081 of 14 December 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards substances in tattoo inks or permanent make-up.

List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

None of the ingredients are listed.

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

None of the ingredients are listed.

Water Framework Directive (WFD)

List of pollutants (WFD)

Name of substance	CAS No	Listed in	Remarks
Titanium dioxide		a)	
Titanium dioxide		a)	

Legend

A) Indicative list of the main pollutants

Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

15.2 Chemical safety assessment

The Chemical Safety Assessment is not required for the mixture.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
Carc.	Carcinogenicity
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances

Abbr.	Descriptions of used abbreviations
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties. The classification is based on tested mixture.
Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H351	Suspected of causing cancer.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.