

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU

dline AG, Holzmoosrütistrasse 48, CH-8820 Wädenswil

HG-HämorrhoidalGel

article number: **20000**

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	HG-HämorrhoidalGel
	Chemical name:	Electrolitically produced sodium hypochlorite
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Helps prevent the risk of bacterial contamination.
	Uses advised against:	Do not use if sensitive or allergic to chlorine compounds.
	Reason why uses advised against:	
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	Cosmetolab AG
	Address:	Holzmoosrütistrasse 48, 8820 Wädenswil, Switzerland
	Telephone number:	+41 (0)44 783 78 00
	Telefax:	
	e-mail of competent person:	info@cosmetolab.ch
	National contact:	info@cosmetolab.ch
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+41442515151
	Other information:	

SECTION 2. Hazards identification		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statement*:
	Not classified as hazardous	Solution less than 5%: Not classified
2.1.2.	Additional information	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
	Product identification:	Not applicable

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Identification number:	Not applicable
Authorisation number:	Not applicable
Hazard pictograms:	Not applicable
Signal word:	Not applicable

Hazard statement:	Not applicable
Precautionary statement:	Not applicable
Supplemental hazard information (EU):	Not classified as hazardous
2.3. Other hazards	
None	

SECTION 3. Composition/information on ingredients

CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
7681-52-9 / 231-668-3 /017-011-00-1	01-2119488154- 34-xxx	0,20% - 0,25%	Sodium hypochlorite	Not classified as hazardous

SECTION 4. First aid measures

4.1. Description of first aid measures	
General notes:	Take off all contaminated clothing. Self-protection of the first aider.
Following inhalation:	If breathing problems occur seek fresh air immediately.
Following skin contact:	Immediately flush skin with plenty of water.
Following eye contact:	Immediately flush eyes with plenty of water. If irritation persists, seek medical attention.
Following ingestion:	If swallowed, drink a large quantities of milk or gelatin solution. If these are not available, drink large quantities of water and call a physician. Do not give vinegar or other acids. Do not induce vomiting.
Self-protection of the first aider	None
4.2. Most important symptoms and effects, both acute and delayed	
Following inhalation:	None known.

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	Following skin contact:	None known
	Following eye contact:	None known
	Following ingestion:	None known
4.3.	Indication of any immediate medical attention and special treatment needed	
	None.	

SECTION 5. Firefighting measures

5.1. Extinguishing media

	Suitable extinguishing media:	Co-ordinate fire-fighting measures to the fire surroundings water spray, foam, dry extinguishing powder, carbon dioxide (CO ₂)
	Unsuitable extinguishing media:	water jet
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	In case of fire may be liberated: hydrogen chloride (HCl), chlorine (Cl ₂), May produce toxic fumes of carbon monoxide if burning.
5.3.	Advice for firefighters	
	Do not allow firefighting water to enter drains or water courses. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus. Wear full chemical protective clothing.	
5.4.	Additional information	
	None.	

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SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Provision of sufficient ventilation. Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe vapour/spray.
	Accident prevention methods:	Prevent rupture and release of sodium hypochlorite from containers.
	Emergency procedures:	None
6.1.2.	For emergency responders:	
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	
6.3.1.	Bunding, covering of drains; capping procedures:	Covering of drains.
6.3.2.	Cleaning up:	Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
6.3.3.	Other information:	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	
7.1.1.	Protective measures	
	Measures to prevent fire:	Handle and open container with care. Provide adequate ventilation

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	Measures to prevent aerosol and dust generation:	Handle and open container with care. Provide adequate ventilation
	Measures to protect the environment:	The product should be diluted with water before disposal in sanitary sewer.
	Other measures:	None.
7.1.2.	Advice on general occupational hygiene:	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Protect from sunlight. Due to gaseous decomposition products, overpressure can occur in tightly sealed containers.
	Packaging materials:	Keep only in the original container.
	Requirements for storage rooms and vessels:	Use local and general ventilation.
	Advices for storage equipment:	None.
	Further information on storage conditions:	Recommended storage temperature: 5 – 25 °C.
7.3.	Specific end use(s)	
	Recommendations:	No information available.
	Industrial sector specific solutions:	No information available.

SECTION 8. Exposure controls/personal protection

8.1.	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
Sodium hypochlorite	7681-52-4	HG-HämorrhoidalGel		This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

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Substance:	Sodium hypochlorite			
EC No:	231-668-3	CAS No:	7681-52-9	
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral			0,26mg/kg	0,26mg/kg
Inhalation	3,1 mg/m³	3,1 mg/m³	1,55 mg/m³	1,55 mg/m³
Dermal	3,1 mg/m³	3,1 mg/m³	1,55 mg/m³	1,55 mg/m³
Critical physical parameters: solubility, flammability, corrosivity:				
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral			0,26mg/kg	0,26mg/kg
Inhalation	3,1 mg/m³	3,1 mg/m³	1,55 mg/m³	1,55 mg/m³
Dermal	Not be derived	Not be derived	Not be derived	Not be derived
PNEC				
Environmental protection target		PNEC		
Fresh water		0,21 µg/L		
Freshwater sediments		0.00021 mg/l		
Marine water		0,42 µg/L		
Marine sediments		0,03 µg/L		
Food chain		not applicable		
Microorganisms in sewage treatment		4,69 mg/L		
Soil (agricultural)		not applicable		
Air		not applicable		
8.2.	Exposure controls			
8.2.1.	Appropriate engineering controls			
	Substance/mixture related measures to prevent exposure during identified uses:		Not relevant for this material.	

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	Structural measures to prevent exposure:	Not relevant for this material.
	Organisational measures to prevent exposure:	Not relevant for this material.

	Technical measures to prevent exposure:	Not relevant for this material.
8.2.2.	Personal protection equipment:	
8.2.2.1.	Eye and face protection:	Not normally required or Safety glasses with side shields
8.2.2.2.	Skin protection:	Not normally required.
	Hand protection:	The use of resistant protective gloves is recommended.
	Other skin protection:	Laboratory coat.
8.2.2.3.	Respiratory protection:	Not normally required.
8.2.2.4.	Thermal hazards:	Not normally required.
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	No special measures are required.
	Structural measures to prevent exposure:	No special measures are required.
	Organisational measures to prevent exposure:	No special measures are required.
	Technical measures to prevent exposure:	No special measures are required.

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SECTION 9. Physical and chemical properties			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	Liquid/gel	
	Colour:	transparent	
	Odour:	Like: chlorine	
	Odour threshold;	Not data available	
	pH:	8,5-10,5	
	Melting point / freezing point;	-25°C	
	Initial boiling point and boiling range:	98°C	
	Flash point:	Not determined	
	Evaporation rate:	No data available	
	Flammability (solid, gas):	Not relevant (fluid)	
	Upper/lower flammability or explosive limits:	This information is not available	

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	Vapour pressure:	This information is not available	
	Vapour density:	This information is not available	
	Relative density	1,032 g/cm ³	
	Bulk density:	Not applicable	
	Solubility(ies):	Complete in water	
	Partition coefficient: n-octanol/water (log Kow):	-3,42 (20 °C)	
	Auto-ignition temperature:	Not available	
	Decomposition temperature:	>111°C	
	Viscosity:	No data	
	Explosive properties:	Shall not be classified as explosive	
	Oxidising properties:	none	
9.2.	Other information		
	None		

SECTION 10.: Stability and reactivity

10.1.	Reactivity:	Contact with acids liberates toxic gas. Mixture corrosive to metals.
10.2.	Chemical stability:	Stable under normal conditions, Sensitivity to light. May lose potent if frozen or stored at high temperature
10.3.	Possibility of hazardous reactions:	Strong oxidizing agent. May bleach clothing.
10.4.	Conditions to avoid:	Keep away from heat, direct sunlight and incompatibles.
10.5.	Incompatible materials:	Acids. Strong oxidizing agents. Metals. Amines.
10.6.	Hazardous decomposition products:	See section 5.

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SECTION 11. Toxicological information					
11.1. Information on toxicological effects					
Acute toxicity:					
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	standard acute method	rat	12,5%	14 days	1.100 mg/kg
Dermal:	standard acute method	rabbit	12,5%	14 days	>20 000 mg/kg

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Inhalation:	standard acute method	rat	10,5 mg/L	1 sat	> 10.5 mg/L air	
	Specific target organ toxicity – single exposure (STOT SE): shall not be calssified as a specific target organ toxicant					
	Specific effects			Target organ	Note	
Oral:	Not applicable.			None known		
Dermal:	Not applicable.			None known		
Inhalation:	Not applicable.			None known		
	Aspiration hazard:		shall not be calssified as a presenting an aspiration hazard.			
	Irritation and corrosion:					
	Exposure time	Species	Evaluation	Method	Note	
Skin corrosion/irritation	4 hours	Rabbit, guinea pig		FHSA procedure	Was slightly irritant	
Serious eye damage/irritation	No data	No data	No data	No data	No data	
	Sensitization					
Skin sensitization:	Not skin sensitisng					
Respiratory sensitization:	No data available.					
	Symptoms related to the physical, chemical and toxicological characteristics					
Oral exposure:	No data available.					
Dermal exposure:	No data available.					
Inhalation exposure:	No data available.					
Eye exposure:	No data available.					
	Repeated dose toxicity (subacute, subchronic, chronic)					
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No data avaiable.	No data available	No data avaiable.	No data avaiable.	No data avaiable.	No data avaiable.

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Subacute dermal	No data avaiable.	No data available	No data avaiable.	No data avaiable.	No data avaiable.	No data avaiable.
Subacute inhalation	No data avaiable.	No data available	No data avaiable.	No data avaiable.	No data avaiable.	No data avaiable.

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Subchronic oral	No data available.	No data available	No data available.	No data available.	No data available.	No data available.
Subchronic dermal	No data available.	No data available	No data available.	No data available.	No data available.	No data available.
Subchronic inhalation	No data available.	No data available	No data available.	No data available.	No data available.	No data available.
Chronic oral	No data available.	No data available	No data available.	No data available.	No data available.	No data available.
Chronic dermal	No data available.	No data available	No data available.	No data available.	No data available.	No data available.
Chronic inhalation	No data available.	No data available	No data available.	No data available.	No data available.	No data available.
	Specific target organ toxicity – repeated exposure (STOT RE):					
	Specific effects		Target organ		Note	
Subacute oral	No data available		None known			
Subacute dermal	No data available		None known			
Subacute inhalation	No data available		None known			
Subchronic oral	No data available		None known			
Subchronic dermal	No data available		None known			
Subchronic inhalation	No data available		None known			
Chronic oral	No data available		None known			
Chronic dermal	No data available		None known			
Chronic inhalation	No data available		None known			
	CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)					
	Carcinogenicity:		not classified cancerogenic according to 67/548/EEC and CLP.			
	Mutagenicity <i>in-vitro</i> :		Mutagenic effects were found in some of the in-vitro studies carried out with NaOCl solution.			
	Genotoxicity:		negative			
	Mutagenicity <i>in-vivo</i> :		Mutagenic effects could not be found in -vivo with NaOCl solution.			
	Germ cell mutagenicity :					
	Reproductive toxicity:		Not show any influence on fertility or developmental toxic effects.			

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	Summary of evaluation of the CMR properties; :	not to be classified mutagenic according to Council Directive 67/548/EEC and CLP.
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11.2.	Practical experiences:	
	Classification observations:	None
	Other observations:	None
11.3.	General notes:	
	None	

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SECTION 12. Ecological information						
12.1. Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish:	LC ₅₀	96 hours	No data available	No data available	No data available	No data available
Crustacea:	EC ₅₀	48 hours	No data available	No data available	No data available	No data available
Algae/aquatic plants:	IC ₅₀	72 hours	No data available	No data available	No data available	No data available
Other organisms:			No data available	No data available	No data available	No data available
Chronic (long-term) toxicity	Doza	Exposure time	Species	Method	Evaluation	Note
Fish:	LC ₅₀	96 hours	No data available	No data available	No data available	No data available
Crustacea:	EC ₅₀	48 hours	No data available	No data available	No data available	No data available
Algae/aquatic plants:	IC ₅₀	72 hours	No data available	No data available	No data available	No data available
Other organisms:			No data available	No data available	No data available	No data available
12.2. Persistence and degradability						
Abiotic degradation						
	Degradation half-lives		Method	Evaluation		Note
Marine water	No data available		No data available	No data available		No data available
Fresh water	No data available		No data available	No data available		No data available

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Air		No data available		No data available		No data available		No data available		
Soil		No data available		No data available		No data available		No data available		
Biodegradation										
% Degradation		Time (days)		Method		Evaluation		Note		
No data available		No data available		No data available		No data available		No data available		
No data available		No data available		No data available		No data available		No data available		
No data available		No data available		No data available		No data available		No data available		
12.3. Bioaccumulative potential										
Octanol-water partition coefficient (log Kow)										
Value		Concentration		pH	°C	Method		Evaluation		Note
No data available		No data available		No data	No data	No data available		No data available		
No data available		No data available		No data	No data	No data available		No data available		
No data available		No data available		No data	No data	No data available		No data available		
Bioconcentration factor (BCF)										
Value		Species		Method		Evaluation		Note		
No data available		No data available		No data available		No data available		No data available		
No data available		No data available		No data available		No data available		No data available		
No data available		No data available		No data available		No data available		No data available		
Chronic ecotoxicity										

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Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀					
Chronic toxicity on crustacea (Daphnia)	EC ₅₀					

12.4. Mobility in soil						
	Known or predicted distribution in environmental compartments:					
	Solubility in water: Completely					
	Surface tension:					
	Value	°C	Concentration	Method	Note	
	No data available	No data available	No data available	No data available	No data available	
	No data available	No data available	No data available	No data available	No data available	
	No data available	No data available	No data available	No data available	No data available	
	Adsorption/desorption					
Transport	A/D coefficient Henry's constant		log Kow	Evaporation rate	Method	Note
Soil-Water	No data available		No data available	No data available	No data available	No data available
Water-Air	No data available		No data available	No data available	No data available	No data available
Soil-Air	No data available		No data available	No data available	No data available	No data available
12.5. Results of PBT and vPvB assessment						
	Data are not available.					

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12.6.	Other adverse effects
	Data are not available.

SECTION 13. Disposal considerations	
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Dispose of contents/container in accordance with local/regional/national/international regulations.
13.1.2.	Waste codes/waste designations according to Low:
	Aluminium tube: 17 04 02; Paper and cardboard: 20 01 01; Plastic packaging: 20 01 39

13.1.3.	Waste treatment – relevant information:
	Completely biodegradable. Dilute with water. Not dangerous for the environment.
13.1.4.	Sewage disposal – relevant information:
	Disposal of the product must be in compliance with the local laws about Active Chlorine and Chlorides in the sinks and sewers.
13.1.5.	Other disposal recommendations:
	Waste shall be separated into the categories that can be handled separately by local or national waste management facilities. Please consider the relevant national or regional provisions.
13.1.6.	Relevant Community provisions:
	The allocation of waste identity numbers/waste description must be carried out according to the EPA, specific to the industry and process.

SECTION 14. Transport information	
	Transporting/shipment by road (ADR)
UN number:	Not applicable.
UN proper shipping name:	Not applicable.

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Transport hazard class(es):	Not classified as dangerous for transport.
Packing group:	Not applicable.
Environmental hazards:	Not applicable.
Special precautions for user:	Not applicable.
Transporting/shipment by rail (RID)	
UN number:	Not applicable.
UN proper shipping name:	Not applicable.
Transport hazard class(es):	Not classified as dangerous for transport.
Packing group:	Not applicable.
Environmental hazards:	Not applicable.
Special precautions for user:	Not applicable.
Transporting/shipment by inland waterways (ADN)	
UN number:	Not applicable.
UN proper shipping name:	Not applicable.
Transport hazard class(es):	Not classified as dangerous for transport.
Packing group:	Not applicable.
Environmental hazards:	Not applicable.
Special precautions for user:	Not applicable.

Transporting/shipment by sea (IMDG)	
UN number:	Not applicable.
UN proper shipping name:	Not applicable.
Transport hazard class(es):	Not classified as dangerous for transport.
Packing group:	Not applicable.
Environmental hazards:	Not applicable.
Special precautions for user:	Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	Not applicable.
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	Not applicable.
UN proper shipping name:	Not applicable.

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Transport hazard class(es):	Not classified as dangerous for transport.
Environmental hazards:	Not applicable.
Special precautions for user:	Not applicable.
Further information:	None

SECTION 15. Regulatory information

15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorisations and/or restrictions on use	
	Authorisations:	No data
	Restrictions:	No data
	Other EU regulations:	CLP classification according to Annex VI of CLP (Regulation (EC) No 1272/2008) REACH Regulation (EC) No 1907/2006 Annex XVII; status - September 2012 EU Directive 67/548/EC and GHS/CLP EWC European Waste Catalogue and Hazardous Waste List
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	The law of chemicals Rules on the conditions for production, placing on the market and use of dangerous chemicals.
15.2.	Chemical safety assessment	
	No data available	

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SECTION 16. Other information		
16.1.	Indication of changes:	Does not have
16.2.	Abbreviations and acronyms:	CLP –Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures REACH –Registration, Evaluation, Authorisation and Restriction of Chemicals ECHA – European Chemical Agency EINECS – European List of Notified Chemical Substances EWC - European Waste Catalogue EPA - Environmental Protection Agency
16.3.	Key literature references and source of data:	SDS of manufacturer ECHA EINECS
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	Not hazardous	
16.5.	Relevant H statements (number and full text)	
	H: none	
16.6.	Training advice:	None
16.7.	Further information:	This information is based on current knowledge. This SDS is made exclusively for this product.

ANNEX: Exposure scenario resulting to Chemical safety assessment

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 .

Disclaimer

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Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU

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End of Safety Data Sheet