



DR. HENNING

WALLDORF GMBH

USt-IdNr.: DE 811121748
Steuer-Nr. 32462 / 29902

Dr. Georg Friedrich Henning GmbH • Postfach 1232 • D-69183 Walldorf

TO WHOM IT MAY CONCERN

10/2015

**Product Information for Chloraethyl Dr. Henning ®,
a Medical Device Class I accord. to Directive 93/42/EEC**

Dear Sir or Madam,

According to Title I, Article 2, Paragraph 6(c) of Directive 1907/2006 shall Title IV of the aforesaid Directive ("INFORMATION IN THE SUPPLY CHAIN") not apply to final products in the form of Medical Devices, intended for the final user.

The attached information **IS NOT** a Material Safety Data Sheet, but rather a voluntary Product Information based on the format of a Safety Data Sheet, and provides information for transportation and storage purposes of Chloraethyl Dr. Henning ® **in bulks only**.

For handling of small volumes up to 175 ml apply both, the safety and user instructions as stated on each sales packaging and in the Patient Information Leaflet (PIL), enclosed to each sales packaging as well.

With kind regards,
Dr. Georg Friedrich Henning
Chemische Fabrik Walldorf GmbH

Chemische Fabrik Walldorf GmbH

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Sparkasse
Heidelberg
Konto-Nr. 57 703 440
(BLZ 672 500 20)

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

This MSDS is exclusively for hazard informations of health professionals.

us-ghs

1.1 Product identifier

Trade name: Chloraethyl Dr. Henning®

Reference-no.: 1500.000.01.V04

Article-No.: --

Chemical name: Chlorethan

CAS Number:

75-00-3

EC-number:

200-830-5

Index number:

602-009-00-0

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

This product may only be used in the manner provided. A liability for improper application is excluded.

Sector of Use:

SU20 Health services

SU22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Product category:

PC 0 UCN 15100 Propellants

PC 0 UCN 20080 Anaesthesia

Process category: PROC11 Non industrial spraying

Environmental release category:

ERC08a Wide dispersive indoor use of processing aids in open systems


ERC08d Wide dispersive outdoor use of processing aids in open systems

ERC10b Wide dispersive outdoor use of long-life articles and materials with high or intended release (including abrasive processing)

ERC11b Wide dispersive indoor use of long-life articles and materials with high or intended release (including abrasive processing)

Article category: AC -

Application of the substance / the preparation:

 (Please note the application instructions.)

Medical cooling spray (Medical device)

Uses advised against: Currently not defined.

1.3 Details of the supplier of the safety data sheet**Manufacturer / Supplier:**

Dr. Georg Friedrich Henning
Chemische Fabrik Walldorf
Robert-Bosch-Strasse 62
D-69190 Walldorf

Informing department:

☎ -49- 6227 / 1278

(info@henning-walldorf.com)

FAX -49- 6227 / 30481

1.4 Emergency telephone number

Manufacturer / Supplier: ☎ -49- 6227 / 1278

(Mon - Thu: 8:00 - 16:00; Fri: 08:00 - 12:00)

Emergency Center:


☎ 1-888-222-13 73 or 911

SECTION 2: Hazard(s) identification**2.1 Classification of the substance or mixture:****Classification according to Regulation (EC) No 1272/2008 [CLP]:**

This product is not subject to classification according to the exception in Article 1.(5) CLP regulation.

 Flame

Flam. Aerosol 1 H222-H229 Extremely flammable aerosol. Pressurized container: May burst if heated.

 Health hazard

Carc. 2 H351 Suspected of causing cancer.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

2.2 Label elements:

2.2.1 Labelling according to Regulation (EC) No 1272/2008 [CLP]: The substance is classified and labeled according to the CLP regulation.

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Material Safety Data Sheet

according to 1907/2006/EC, Article 31 and ISO/DIS 11014

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Trade name: **Chloraethyl Dr. Henning®**

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Hazard pictograms:

(See section 2)

GHS02, GHS08

Signal word: Danger

Hazard-determining components of labelling:

Chloroethane, medical

Hazard statements:

H222-H229 Extremely flammable aerosol. Pressurized container: May burst if heated.

H351 Suspected of causing cancer.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P251 Do not pierce or burn, even after use.

P211 Do not spray on an open flame or other ignition source.

P280 Wear protective gloves / eye protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.2.3 Information pertaining to particular dangers for man and environment:

The vapours of the product are heavier than air and may accumulate on the ground, in mines, drains or cellars with higher concentration. Heightened risk of fire and danger of explosion at accumulation in lower-lying or closed rooms.

2.3 Other hazards There are no other hazards known.

Results of PBT and vPvB assessment: Not applicable.

PBT: Not applicable.

vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.1 Chemical characterization: Substances

CAS No. Designation:

75-00-3 Chloroethane, medical

Identification number(s):

EC-number: 200-830-5

Index number: 602-009-00-0

Dangerous components:

CAS No.

Designation / Identification

CAS: 75-00-3

Chloroethane, medical

EINECS: 200-830-5

Index number: 602-009-00-0

RTECS: KH 7525000

Reg.nr.: 01-2119487479-17-

⚠ Flam. Aerosol 1, H222-H229: ⚠ Carc. 2, H351; Aquatic Chronic 3, H412

%
95 - 100%

SECTION 4: First-aid measures

4.1 Description of first aid measures:

4.1.1 General information:

✚ Remove the victim immediately from the danger area.
If the patient is unwell consult a doctor and present this data sheet.
Instantly remove any clothing soiled by the product.

4.1.2 After inhalation: Supply fresh air; consult doctor in case of symptoms.

4.1.3 After skin contact: The product does not, generally speaking, cause skin irritation. Wash with water and soap and rinse well.

4.1.4 After eye contact:

First, blow on the solution to speed up evaporation. Seek medical treatment.
Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

4.1.5 After swallowing: In case of persistent symptoms consult doctor.

4.2 Information for doctor:

✚ The following instructions are only for emergency medical treatment.
They may not be performed by first responders.

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4.2.1 Most important symptoms and effects, both acute and delayed:

Headache
Dazed
Freeze burns


4.2.2 Risks: Danger of system failure.

4.2.3 Indication of any immediate medical attention and special treatment needed: Monitor circulation.

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

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

For safety reasons unsuitable extinguishing agents: None.

5.2 Special hazards arising from the substance or mixture

Carbon monoxide (CO)
Hydrogen chloride (HCl)
Can form explosive gas-air mixtures.
In the event of fire, combustible gases and vapours are produced.

5.3 Advice for firefighters

5.3.1 Protective equipment:


Do not inhale explosion gases or combustion gases.
Wear self-contained breathing apparatus.

5.3.2 Fire fighting information: Fire residues and contaminated extinguishing water must be disposed of in accordance with official regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

 Keep away from ignition sources.

 Remove unauthorised persons from the danger area.

Provide sufficient ventilation.

6.2 Environmental precautions The product must not get into lakes, rivers or channels, the sewage system or into the soil.

6.3 Methods and material for containment and cleaning up


Ensure adequate ventilation.
Do not rinse away with water or aqueous cleaning agents.
Absorb liquid components with liquid-binding material.
Dispose of contaminated material as waste according to item 13.

6.4 Reference to other sections

See Section 7 for information on safe handling.
See Section 8.2 for information on personal protection equipment.
See Section 13 for information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

 Do not eat, drink or smoke when processing the product.

Ensure good ventilation / exhaust at the workplace.
Keep containers tightly sealed.
Store in cool, dry place in tightly closed containers.
Keep away from heat and direct sunlight.

7.2 Conditions for safe storage, including any incompatibilities

7.2.1 Requirements to be met by storerooms and containers

Store only in the original container.
Observe official regulations on storing packagings with pressurized containers.

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7.2.2 Information about storage in one common storage facility

- ★ Do not store together with food, beverage or animal feed.

Store away from oxidizing agents.

7.2.3 Further information about storage conditions



Protect against frost, severe exposure to the sun and contaminants.

- Maximum storage temperature: 50 °C (122°F)
- Recommended storage temperature: 10 °C to 35 °C (50°F to 95°F)
- Storage class: 2 B

7.3 Specific end use(s) The product intended solely for the application stated in the product description. (See section 1.2)

SECTION 8: Exposure controls/personal protection

Additional information about design of technical systems: Provide good workplace ventilation / air extraction.

8.1 Control parameters

8.1.0 Components with critical values that require monitoring at the workplace

8.1.1 DNELs

The values given for the "Derived no-effect level" are calculated for private consumers individual values. A combined effect of the substances was not considered.

CAS No. Designation of material

75-00-3 Chloroethane, medical

Dermal DNEL 38.3 mg/kg/day (Humans)

Inhalative DNEL 268 mg/m³ (Humans)

8.1.2 PNECs All datas are valid for individual ingredients. A combined effect of the substances was not taken into account.

CAS No. Designation of material

75-00-3 Chloroethane, medical

PNEC 0.058 mg/l (Freshwater)

PNEC 0.3098 mg/kg (Soil)

8.1.3 Workplace exposure limits

CAS No. Designation of material

75-00-3 Chloroethane, medical

IOELV (European Union) Long-term value: 268 mg/m³, 100 ppm

PEL (USA) Long-term value: 2600 mg/m³, 1000 ppm

REL (USA) Handle with caution; See Pocket Guide App. C

TLV (USA) Long-term value: 264 mg/m³, 100 ppm

Skin

8.1.4 Additional Occupational Exposure Limit Values for possible hazards during processing

In the contemplated processing no further exposure limits have to be observed.

8.1.6 Additional informations The applicable national list was used as the basis for the preparation and / or revision of this safety data sheet.

8.2 Exposure controls

8.2.0 Personal protective equipment

The use of protective equipment may be required for commercial use of the product. Type and extent depend on the workplace.

8.2.1 General protective and hygienic measures

Wash hands during breaks and at the end of the work.

Do not eat, drink, smoke or take snuff while working.

Use skin protection cream for preventive skin protection.

Do not inhale aerosols.

Use a moisturising skin cream after processing the product.

8.2.2 Breathing equipment

For extensive application and inadequate ventilation respiratory protection is required.

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8.2.3 Protection of hands

Protective gloves.


The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Check protective gloves prior to each use for their proper condition.
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.

- 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.

 The use of waterproof gloves with little protection Against chemicals is recommended.

- For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

0.2 - 0.4 mm: ≤ 120 min.
Butyl rubber, BR
Fluorocarbon rubber (Viton)
Nitrile rubber, NBR

- For the permanent contact gloves made of the following materials are suitable:

0.5 - 0.7 mm: 120 - 240 min.
Butyl rubber, BR
Fluorocarbon rubber (Viton)
Nitrile rubber, NBR
Chloroprene rubber, CR
Neoprene gloves.

- Not suitable are gloves made of the following materials:



Natural rubber, NR
Rubber gloves

8.2.4 Eye protection

Safety glasses.

8.2.5 Body protection

Protective work clothing.

Solvent resistant protective clothing
Impervious protective clothing

8.3 Limitation and supervision of exposure into the environment

At this point no data are available.

8.4 Risk management measures

There are no measures established for the risk management of ingredients according to Article 32 of Regulation (EC) No 1907/2006.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

The following physical data are subject to normal fluctuations of raw materials and in the production.

General Information

Appearance:

Form:

Aerosol

Colour:

Colourless

Smell:

Ether-like

pH-value:

Not applicable.

Flashpoint:

-43 °C (-45 °F) (DIN 51755 / EN ISO 2719)

Fire behavior:

The product supports combustion.

Inflammability (solid, gaseous):

Extremely flammable liquefied gas.

Self-inflammability:

519 °C

Critical values for explosion:

Lower:

[Highest / lowest value of individual components]

Upper:

3,6 Vol % (DIN 51649)

Oxidizing properties:

14,8 Vol % (DIN 51649)

Steam pressure at 20 °C (68 °F):

Product is not oxidizing.

Density at 13 °C (55 °F):

1343 hPa (1007 mm Hg) (DIN EN 12)

Evaporation rate:

0,91 g/cm³ (7.594 lbs/gal)

Not determined.

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Trade name: **Chloroethyl Dr. Henning®**

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Solubility in / Miscibility with
Water at 20 °C (68 °F):
Flammable components:

5.8 g/l
100.0 %

9.2 Other information:

VOC (EU):

917.1 g/l

VOC (EU):

100.00 %

Remark:

The product is not subject to the VOC Directive 2004/42 EU.

SECTION 10: Stability and reactivity

10.1 Reactivity This product has no / low chemical reactivity.

10.2 Chemical stability The product is in compliance with the storage and processing conditions, chemically stable.
- **Conditions to be avoided:** No decomposition when properly applied and stored.

10.3 Possibility of hazardous reactions

Forms explosive gas mixture with air.
Reacts with strong oxidizing agents
Reacts with alkaline metals
Reacts with light alloys

10.4 Conditions to avoid See section 7.2

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous decomposition products

If handled and stored properly dangerous products of decomposition are not to be expected.
Thermal decomposition: Toxic gases / vapors; highly flammable gases / vapors.
Hydrogen chloride (HCl)
Phosgen

10.7 Additional informations

There is no risk of decomposition or uncontrolled chemical reaction when the specified application conditions are complied with.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

If the substance or the mixture is not classified for a particular hazard, the following notice will be given in the safety data sheet: "Based on available data the classification criteria are not met."

11.1.1 Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values that are relevant for classification (EU):

With this product no toxicological studies were performed on living organisms. The following data are literature values of individual ingredients that have no claim to completeness.

Components	Type	Value	Species
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75-00-3 Chloroethane, medical

Inhalative LC 50/4 >19000 mg/l/4h (rat)

11.1.2.1 Primary irritant effect

- **On the skin:** Skin irritation possible due to drying effect.

- **On the eye:** Based on available data, the classification criteria are not met.

- **Sensitization:** Based on available data, the classification criteria are not met.

OSHA-Ca (Occupational Safety & Health Administration)

Substance is not listed.

- **Repeated dose toxicity:** Not tested.

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction) (EU):**

The product contains CMR substances (see chapter 3). There have been no formal testing.

CAS No.

Designation

%

75-00-3 Chloroethane, medical

SECTION 12: Ecological information

12.1 Toxicity

Aquatic Toxicity: The following values were obtained from the literature.

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CAS Chemical name
Type of test Effective concentration (Species)
75-00-3 Chloroethane, medical
LC 50/96h 58 mg/l (Daphnia magna)
EC 50/72h 39 mg/l (Alge)
118 mg/l (Scenedesmus subspicatus)

12.2 Persistence and degradability

Other notes: The product has good biodegradable properties.

Bioaccumulative potential The following data were taken from the literature.

CAS Chemical name
Type of test Effective concentration
75-00-3 Chloroethane, medical
Bioakkumulation 1.43 log Pow (n.a)

12.4 Mobility in soil No further relevant information available.

12.4.3 Additional ecological informations
COD-value: No data available.

BOD-value: No data available.

According to the formulation contains the following heavy metals and compounds from the EU guideline NO. 2006/11/EC:
Halogenated hydrocarbons

General notes:
Do not allow product to reach ground water, water bodies or sewage system.
Harmful to aquatic organisms

12.5 Results of PBT and vPvB assessment Not applicable.

12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation:

After prior treatment product has to be disposed of in an incinerator for hazardous waste under adherence to the regulations pertaining to the disposal of particularly hazardous waste.

European waste catalogue:

- 14 00 00 WASTE ORGANIC SOLVENTS, REFRIGERANTS AND PROPELLANTS (except 07 and 08)
- 14 06 00 waste organic solvents, refrigerants and foam/aerosol propellants
- 14 06 02* other halogenated solvents and solvent mixtures
- 15 00 00 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED
- 15 01 00 packaging (including separately collected municipal packaging waste)
- 15 01 04 metallic packaging
- 15 00 00 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED
- 15 01 00 packaging (including separately collected municipal packaging waste)
- 15 01 07 glass packaging

Recommended cleaning agent:

Cleaning by recycler.
Water, if necessary with cleaning agent.

13.1.3 Cleaned / empty containers

 Packaging, which have no harmful residues of the product can be recycled.

SECTION 14: Transport information

14.1 UN-Number
IMDG, IATA

UN1950

14.2 UN proper shipping name
ADR/RID
IMDG, IATA

1950 Aerosols
AEROSOLS

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14.3 Transport hazard class(es)

Class

2 F Gases.

Label

2.1

IMDG, IATA



Class

2 Gases.

Label

2.1

14.4 Packing group:

IMDG, IATA

Void

14.5 Environmental hazards

Marine pollutant:

No

14.6 Special precautions for user

EMS-Number:

Warning: Gases.

Segregation groups:

F-D.S-U

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

14.8 Additional Informations:

Remarks:

None

Excepted quantities (EQ):

Code: E0

Limited quantities (LQ)

Not permitted as Excepted Quantity

Excepted quantities (EQ)

IL

Code: E0

Not permitted as Excepted Quantity

IATA

Comments:

Please note the general and specific packing instructions of IATA / ICAO.

PI Ltd Qty:

Y 203



PI Pass.:

203

PI Cargo:

203

14.9 UN "Model Regulation":


UN 1950 AEROSOLS, 2.1

SECTION 15: Regulatory information

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

15.1.4 National regulations

National regulations are to be determined by the user's own responsibility.

 This product is approved as a medical device.

US Listings:

TSCA (Toxic Substances Control Act):

Substance is listed.

15.2 Chemical safety assessment A Chemical Safety Assessment has been carried out.

SECTION 16: Other informations

The above details are based on the latest state of our knowledge. Processing notes for this product are listed in a technical data sheet. Existing laws, decrees and regulations, even those which are not stated in this data sheet are to be complied by the recipient of our products at his own responsibility.

Reasons for changes: 4.ATP; 5.ATP, 6.ATP, 7.ATP

Relevant phrases:


H222 Extremely flammable aerosol.

H229 Pressurized container: May burst if heated.

H351 Suspected of causing cancer.

H412 Harmful to aquatic life with long lasting effects.

Training hints:

 In case of commercial use, employees are to be informed about the potential dangers every year.

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Material Safety Data Sheet issued by:

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Note:

The informations about ingredients given in this data sheet are basing on the informations of our suppliers of raw materials. Despite careful handling, the completeness and correctness of these data can not be guaranteed. This is especially true for substances below their declaration limit and for substances without classification or without attribution to a CAS number.

Physical data were identified by the manufacturer of this product. They represent no assurance of product characteristics and establishes no legal contractual relationship.

The validity of this safety data sheet expires one year after its release.

Abbreviations and acronyms:

IOELV: Indicative Occupational Exposure Limit Value (EU)
ECHA: European Chemicals Agency
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Aerosol 1: Flammable aerosols, Hazard Category 1
Carc. 2: Carcinogenicity, Hazard Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

[*] Those chapters marked with (*) were changed to the previous version of this MSDS.

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