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

1.1 Product identifier

Genius HC

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

1.2.1 Relevant uses

Medical product
Dialysis concentrate

1.2.2 Uses advised against

None known.

1.3 Details of the supplier of the safety data sheet

Company

Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Str.1
61352 Bad Homburg / GERMANY
Phone +49 (0)6172-609-0
Fax +49 (0)6172-609-2512
Homepage www.fmc-ag.com

Manufacturer

Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Str.1
61352 Bad Homburg / GERMANY
Phone +49 (0)6172-609-0
Fax +49 (0)6172-609-2512
Homepage www.fmc-ag.com

Address enquiries to

Technical information

Safety Data Sheet sdb@chemiebuero.de (No dispatch of safety data sheets)

Safety data sheets are available from the supplier.

1.4 Emergency telephone number

Company +49 (0)6172-609-0 Mo-Fr 8:00 - 16:00

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture [REGULATION (EC) No 1272/2008]

Met. Corr. 1: H290 May be corrosive to metals.

2.2 Label elements

This preparation is excluded as medical product from the regulation 1272/2008 (CLP Article 1 (5)).

2.3 Other hazards

Human health dangers Frequent persistent contact with the skin can cause skin irritation.
Contains no ingredients with endocrine-disrupting properties.

Environmental hazards Does not contain any PBT or vPvB substances.

Other hazards Further hazards were not determined with the current level of knowledge.

SECTION 3: Composition / Information on ingredients

3.1 Substances

not applicable

3.2 Mixtures

The product is a mixture.

Range [%]	Substance
1 - < 3	Calcium chloride dihydrate
	CAS: 10035-04-8, EINECS/ELINCS: 233-140-8, Reg-No.: 01-2119494219-28-XXXX
	GHS/CLP: Eye Irrit. 2: H319
< 1	Hydrochloric acid
	CAS: 7647-01-0, EINECS/ELINCS: 231-595-7, EU-INDEX: 017-002-01-X, Reg-No.: 01-2119484862-27-XXXX
	GHS/CLP: Skin Corr. 1A: H314 - Eye Dam. 1: H318 - STOT SE 3: H335 - Met. Corr. 1: H290
	SCL [%]: >=10 - <25: Skin Corr. 1B: H314, >= 10: STOT SE 3: H335, >= 1: Eye Dam. 1: H318, >= 25: Skin Corr. 1A: H314, >= 0.1: Met. Corr. 1: H290

Comment on component parts For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information Take off contaminated clothing and wash before reuse.

Inhalation Ensure supply of fresh air.
In the event of symptoms seek medical treatment.

Skin contact When in contact with the skin, clean with soap and water.

Eye contact Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

Ingestion Rinse out mouth and give plenty of water to drink.
Seek medical advice immediately.

4.2 Most important symptoms and effects, both acute and delayed

Irritant effects

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media Product itself is non-combustible. Fire extinguishing method of surrounding areas must be considered.

Extinguishing media that must not be used Full water jet.

5.2 Special hazards arising from the substance or mixture

Risk of formation of toxic pyrolysis products.
Hydrogen chloride (HCl).

5.3 Advice for firefighters

Use self-contained breathing apparatus.

Fire residues and contaminated firefighting water must be disposed of in accordance within the local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

High risk of slipping due to leakage/spillage of product.
Use personal protective clothing.

6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater.
Prevent spread over a wide area (e.g. by containment or oil barriers).

6.3 Methods and material for containment and cleaning up

Take up with absorbent material (e.g. acid binder).
Dispose of absorbed material in accordance within the regulations.

6.4 Reference to other sections

See SECTION 8+13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

The normal safety precautions for handling chemicals must be observed.

Wash hands before breaks and after work.
Use barrier skin cream.
Take off contaminated clothing and wash before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Provide acid-resistant floor.
Keep only in original container.
Prevent penetration into the ground.

Do not store together with food and animal food/diet.

Keep container tightly closed.
Protect from heat/overheating.

7.3 Specific end use(s)

See product use, SECTION 1.2

SECTION 8: Exposure controls / personal protection

8.1 Control parameters

Ingredients with occupational exposure limits to be monitored (EU)

Substance / EC LIMIT VALUES
Hydrochloric acid
CAS: 7647-01-0, EINECS/ELINCS: 231-595-7, EU-INDEX: 017-002-01-X, Reg-No.: 01-2119484862-27-XXXX
Eight hours: 5 ppm, 8 mg/m³
Short-term (15-minute): 10 ppm, 15 mg/m³

DNEL

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
Industrial, inhalative, Long-term - local effects, 5 mg/m³
Industrial, inhalative, Acute - local effects, 10 mg/m³
general population, inhalative, Long-term - local effects, 2.5 mg/m³
general population, inhalative, Acute - local effects, 5 mg/m³
Hydrochloric acid, CAS: 7647-01-0
Industrial, inhalative, Long-term - local effects, 8 mg/m³
Industrial, inhalative, Acute - local effects, 15 mg/m³
general population, inhalative, Acute - local effects, 8 mg/m³
general population, inhalative, Acute - local effects, 15 mg/m³

PNEC

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
There are no PNEC values established for the substance.
Hydrochloric acid, CAS: 7647-01-0
There are no PNEC values established for the substance.

8.2 Exposure controls

Additional advice on system design	Ensure adequate ventilation on workstation.
Eye protection	safety glasses (EN 166:2001)
Hand protection	0.4 mm; Butyl rubber, >120 min (EN 374-1/-2/-3). The details concerned are recommendations. Please contact the glove supplier for further information.
Skin protection	Protective clothing (EN 340)
Other	Avoid contact with eyes and skin. Personal protective equipment should be selected specifically for the working place, depending on concentration and quantity handled. The resistance of this equipment to chemicals should be ascertained with the respective supplier.
Respiratory protection	Not required under normal conditions.
Thermal hazards	none
Delimitation and monitoring of the environmental exposition	Protect the environment by applying appropriate control measures to prevent or limit emissions.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Form	liquid
Color	colourless
Odor	characteristic
Odour threshold	not determined
pH-value	ca. 3.7
pH-value [1%]	not determined
Boiling point [°C]	not determined
Flash point [°C]	not applicable
Flammability	not applicable
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Oxidising properties	no
Vapour pressure/gas pressure [kPa]	not determined
Density [g/cm³]	not determined
Relative density	not determined
Bulk density [kg/m³]	not applicable
Solubility in water	miscible
Solubility other solvents	No information available.
Partition coefficient [n-octanol/water]	not relevant
Kinematic viscosity	not relevant
Relative vapour density	not relevant
Evaporation speed	not relevant
Melting point [°C]	not determined
Auto-ignition temperature [°C]	not applicable
Decomposition temperature [°C]	not relevant
Particle characteristics	not applicable

9.2 Other information

not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reactions known if used as directed.

10.2 Chemical stability

Stable under normal ambient conditions (ambient temperature).

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

No dangerous reactions known if used as directed.

10.5 Incompatible materials

Alkalies

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

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

Acute oral toxicity

Product
ATE-mix, oral, > 2000 mg/kg

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
LD50, oral, Rat, 3000 mg/kg
Hydrochloric acid, CAS: 7647-01-0
LD50, oral, Rabbit, 900 mg/kg

Acute dermal toxicity

Product
ATE-mix, dermal, > 2000 mg/kg

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
LD50, dermal, Rabbit, > 6500 mg/kg

Acute inhalational toxicity

Product
ATE-mix, inhalative, > 20 mg/l 4h

Substance
Hydrochloric acid, CAS: 7647-01-0
LC50, inhalative, Rat, 45.6 mg/l/5min (Aerosol)
LC50, inhalative, Rat, 8.3 mg/l/30min (Aerosol)

Serious eye damage/irritation Based on the available information, the classification criteria are not fulfilled.

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
Eye, Rabbit, OECD 405, irritant
Hydrochloric acid, CAS: 7647-01-0
Eye, Causes serious eye damage.

Skin corrosion/irritation Based on the available information, the classification criteria are not fulfilled.

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
dermal, Rabbit, OECD 404, non-irritating
Hydrochloric acid, CAS: 7647-01-0
dermal, corrosive

Respiratory or skin sensitisation Based on the available information, the classification criteria are not fulfilled.

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
inhalative, non-sensitizing

dermal, non-sensitizing
Hydrochloric acid, CAS: 7647-01-0
dermal, non-sensitizing

Specific target organ toxicity — single exposure Based on the available information, the classification criteria are not fulfilled.

Substance
Hydrochloric acid, CAS: 7647-01-0
inhalative, irritant

Specific target organ toxicity — repeated exposure Based on the available information, the classification criteria are not fulfilled.

Substance
Hydrochloric acid, CAS: 7647-01-0
NOAEC, inhalative, Rat, 30 mg/m³ (subchronic), The effects observed are not sufficient for classification.

Mutagenicity Based on the available information, the classification criteria are not fulfilled.

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
in vitro, no adverse effect observed
Hydrochloric acid, CAS: 7647-01-0
in vitro, negativ

Reproduction toxicity Based on the available information, the classification criteria are not fulfilled.

- Fertility

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
NOAEL, oral, Rat, 169 mg/kg bw/day, no adverse effect observed

- Development

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
NOAEL, oral, Rat, 169 mg/kg bw/day, no adverse effect observed

Carcinogenicity Based on the available information, the classification criteria are not fulfilled.

Substance
Hydrochloric acid, CAS: 7647-01-0
NOAEC, inhalative, Rat, 15 mg/m³ (chronic), no adverse effect observed

Aspiration hazard Based on the available information, the classification criteria are not fulfilled.

General remarks

Toxicological data of complete product are not available.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties Contains no ingredients with endocrine-disrupting properties.

11.2.2 Other information none

SECTION 12: Ecological information

12.1 Toxicity

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
LC50, (96h), fish, 6000 mg/l
EC50, (72h), Algae, 3800 mg/l
EC50, (48h), Daphnia magna, 3100 mg/l
Hydrochloric acid, CAS: 7647-01-0
LC50, (96h), Lepomis macrochirus, 3.25 mg/l
EC50, (48h), Daphnia magna, 4.92 mg/l

12.2 Persistence and degradability

Behaviour in environment compartments No information available.

Behaviour in sewage plant No information available.

Biological degradability No information available.

12.3 Bioaccumulative potential

Accumulation in organisms is not expected.

12.4 Mobility in soil

Spillages may penetrate the soil causing ground water contamination.

12.5 Results of PBT and vPvB assessment

Based on all available information not to be classified as PBT or vPvB respectively.

12.6 Endocrine disrupting properties

Contains no ingredients with endocrine-disrupting properties.

12.7 Other adverse effects

Do not discharge product unmonitored into the environment or into the drainage.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. It is not possible to determine a waste code for this product in accordance with the European Waste Catalogue (EWC) since it is only possible to classify it according to how it is used by the customer. The waste code is to be determined within the EU in liaison with the waste-disposal operator.

Product

For recycling, consult manufacturer.

Waste no. (recommended) 180106*

Contaminated packaging

Uncontaminated packaging may be taken for recycling.

Waste no. (recommended) 150102
150110* packaging containing residues of or contaminated by hazardous substances

SECTION 14: Transport information

14.1 UN number or ID number

Transport by land according to ADR/RID	1789
Inland navigation (ADN)	1789
Marine transport in accordance with IMDG	1789
Air transport in accordance with IATA	1789

14.2 UN proper shipping name

Transport by land according to ADR/RID	Hydrochloric acid, solution
- Classification Code	C1
- Label	
- ADR LQ	5 l
- ADR 1.1.3.6 (8.6)	Transport category (tunnel restriction code) 3 (E)
Inland navigation (ADN)	Hydrochloric acid, solution
- Classification Code	C1
- Label	
Marine transport in accordance with IMDG	Hydrochloric acid, solution
- EMS	F-A, S-B
- Label	
- IMDG LQ	5 l
Air transport in accordance with IATA	Hydrochloric acid, solution
- Label	

14.3 Transport hazard class(es)

Transport by land according to ADR/RID	8
Inland navigation (ADN)	8
Marine transport in accordance with IMDG	8
Air transport in accordance with IATA	8

14.4 Packing group

Transport by land according to ADR/RID	III
Inland navigation (ADN)	III
Marine transport in accordance with IMDG	III
Air transport in accordance with IATA	III

14.5 Environmental hazards

Transport by land according to ADR/RID	no
Inland navigation (ADN)	no
Marine transport in accordance with IMDG	no
Air transport in accordance with IATA	no

14.6 Special precautions for user

Relevant information under SECTION 6 to 8.

14.7 Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

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

EEC-REGULATIONS	2008/98/EC 2000/532/EC); 2010/75/EU; 2004/42/EC; (EC) 648/2004; (EC) 1907/2006 (REACH); (EU) 1272/2008; 75/324/EEC ((EC) 2016/2037); (EU) 2020/878; (EU) 2016/131; (EU) 517/2014
Comment on component parts	Substances of Very High Concern - SVHC: substances are not contained or are below 0.1%.
- Annex XIV (REACH)	According to Annex XIV of Regulation (EC) 1907/2006 (REACH) the product does not contain any substances ≥ 0.1% that are subject to authorisation.
- Annex XVII (REACH)	According to Annex XVII of Regulation (EC) 1907/2006 (REACH) the product contains ≥ 0.1% of substances with the following restrictions. 3, 75
	According to Annex XVII of Regulation (EC) 1907/2006 (REACH) the product is subject to the following restrictions. 3
TRANSPORT-REGULATIONS	ADR (2023); IMDG-Code (2023, 41. Amdt.); IATA-DGR (2023)
NATIONAL REGULATIONS (EU):	
- Observe employment restrictions for people	no
- VOC (2010/75/CE)	0 %

15.2 Chemical safety assessment

not applicable

SECTION 16: Other information

16.1 Hazard statements (SECTION 3)

H290 May be corrosive to metals.
H335 May cause respiratory irritation.
H318 Causes serious eye damage.
H314 Causes severe skin burns and eye damage.

H319 Causes serious eye irritation.

16.2 Abbreviations and acronyms:

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route
RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses
ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure
ATE = acute toxicity estimate
CAS = Chemical Abstracts Service
CLP = Classification, Labelling and Packaging
DMEL = Derived Minimum Effect Level
DNEL = Derived No Effect Level
EC50 = Median effective concentration
ECB = European Chemicals Bureau
EEC = European Economic Community
EINECS = European Inventory of Existing Commercial Chemical Substances
EL50 = Median effective loading
ELINCS = European List of Notified Chemical Substances
EmS = Emergency Schedules
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC-Code = International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IC50 = Inhibition concentration, 50%
IMDG = International Maritime Code for Dangerous Goods
IUCLID = International Uniform ChemicaL Information Database
IVIS = In vitro irritation score
LC50 = Lethal concentration, 50%
LD50 = Median lethal dose
LC0 = lethal concentration, 0%
LOAEL = lowest-observed-adverse-effect level
LL50 = Median lethal loading
LQ = Limited Quantities
MARPOL = International Convention for the Prevention of Marine Pollution from Ships
NOAEL = No Observed Adverse Effect Level
NOEC = No Observed Effect Concentration
PBT = Persistent, Bioaccumulative and Toxic substance
PNEC = Predicted No-Effect Concentration
REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals
STP = Sewage Treatment Plant
TLV®/TWA = Threshold limit value – time-weighted average
TLV®STEL = Threshold limit value – short-time exposure limit
VOC = Volatile Organic Compounds
vPvB = very Persistent and very Bioaccumulative

16.3 Other information

Classification procedure Met. Corr. 1: H290 May be corrosive to metals. (On basis of test data)

Modified position SECTION 2 been added: Contains no ingredients with endocrine-disrupting properties.

SECTION 11 been added: Contains no ingredients with endocrine-disrupting properties.

SECTION 12 been added: Contains no ingredients with endocrine-disrupting properties.