

**Fresenius Medical Care Australia Pty. Ltd.  
2164 Smithfield NSW**

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****SMARTBAG****1.2 Relevant identified uses of the substance or mixture and uses advised against****1.2.1 Relevant uses**

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 Australia Pty. Ltd.  
305 Woodpark Road  
2164 Smithfield NSW / AUSTRALIA  
Phone +61 2 8788 5900  
Fax +61 2 9725 4164**Manufacturer**Fresenius Medical Care Australia Pty. Ltd.  
305 Woodpark Road  
2164 Smithfield NSW / AUSTRALIA  
Phone +61 2 8788 5900  
Fax +61 2 9725 4164**Address enquiries to****Technical information****Safety Data Sheet**

sdb@chemiebuero.de

**1.4 Emergency telephone number****Advisory body**

13 11 26 (National Poison Line)

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture [REGULATION GHS]**

No classification.

**2.2 Label elements****Hazard pictograms**

none

**Signal word**

none

**Hazard statements**

none

**Precautionary statements**

none

**2.3 Other hazards****Human health dangers**

Frequent persistent contact with the skin can cause skin irritation.

**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	Calcium chloride dihydrate
	CAS: 10035-04-8
	GHS: Eye Irrit. 2A: H319
<1	Acetic acid
	CAS: 64-19-7
	GHS: Flam. Liq. 3: H226 - Skin Corr. 1A: H314 - Eye Dam. 1: H318
	SCL [%]: >=10 - <25: Skin Irrit. 2: H315, >=10 - <25: Eye Irrit. 2: H319, >=25 - <90: Skin Corr. 1B: H314, >= 90: Skin Corr. 1A: H314

#### Comment on component parts

All chemical substances in this material are included on or exempted from listing on the AICS Inventory.  
For full text of H-statements: see SECTION 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

<b>General information</b>	Take off contaminated clothing and wash before reuse.
<b>Inhalation</b>	Ensure supply of fresh air. In the event of symptoms seek medical treatment.
<b>Skin contact</b>	When in contact with the skin, clean with soap and water. Consult a doctor if skin irritation persists.
<b>Eye contact</b>	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.
<b>Ingestion</b>	Rinse out mouth and give plenty of water to drink. Do not induce vomiting. 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

<b>Suitable extinguishing media</b>	Product itself is non-combustible. Fire extinguishing method of surrounding areas must be considered.
<b>Extinguishing media that must not be used</b>	Full water jet

### 5.2 Special hazards arising from the substance or mixture

Risk of formation of toxic pyrolysis products.

### 5.3 Advice for firefighters

Use self-contained breathing apparatus.  
Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

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**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 equipment (protective gloves, safety glasses, protective clothing).

**6.2 Environmental precautions**

Do not discharge into the drains/surface waters/groundwater.

**6.3 Methods and material for containment and cleaning up**

Pick up with absorbent material (e.g. sand, sawdust, universal absorbent, diatomaceous earth).  
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.  
Do not eat, drink, smoke or take drugs at work.  
Take off contaminated clothing and wash before reuse.

**7.2 Conditions for safe storage, including any incompatibilities**

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 (AU)**

not applicable

**DNEL**

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
Industrial, inhalative, Long-term - local effects, 5 mg/m <sup>3</sup>
Industrial, inhalative, Acute - local effects, 10 mg/m <sup>3</sup>
general population, inhalative, Long-term - local effects, 2.5 mg/m <sup>3</sup>
general population, inhalative, Acute - local effects, 5 mg/m <sup>3</sup>
Acetic acid, CAS: 64-19-7
Industrial, inhalative, Acute - local effects, 25 mg/m <sup>3</sup>
Industrial, inhalative, Long-term - local effects, 25 mg/m <sup>3</sup>
general population, inhalative, Acute - local effects, 25 mg/m <sup>3</sup>
general population, inhalative, Long-term - local effects, 25 mg/m <sup>3</sup>

**PNEC**

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
There are no PNEC values established for the substance.
Acetic acid, CAS: 64-19-7
freshwater, 3,058 mg/L
seawater, 0,306 mg/L
sediment (freshwater), 11.36 mg/kg
sediment (seawater), 1,136 mg/kg
soil, 0,47 mg/kg soil dw
sewage treatment plants (STP), 85 mg/l

**8.2 Exposure controls**

<b>Additional advice on system design</b>	Ensure adequate ventilation on workstation.
<b>Eye protection</b>	Safety glasses. (EN 166:2001)
<b>Hand protection</b>	0,75 mm; Chloroprene, >480 min (EN 374-1/-2/-3). The details concerned are recommendations. Please contact the glove supplier for further information.
<b>Skin protection</b>	Protective clothing (EN 340)
<b>Other</b>	Avoid contact with eyes and skin.
<b>Respiratory protection</b>	Not required under normal conditions.
<b>Thermal hazards</b>	none
<b>Delimitation and monitoring of the environmental exposition</b>	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
Color	colourless
Odor	characteristic
Odour threshold	not determined
pH-value	2-3
pH-value [1%]	not determined
Boiling point [°C]	not determined
Flash point [°C]	not applicable
Flammability (solid, gas) [°C]	not applicable
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Oxidising properties	no
Vapour pressure/gas pressure [kPa]	not determined
Density [g/cm <sup>3</sup> ]	1,1 - 1,3 (20 °C / 68,0 °F)
Relative density	not determined
Bulk density [kg/m <sup>3</sup> ]	not applicable
Solubility in water	miscible
Solubility other solvents	No information available.
Partition coefficient [n-octanol/water]	not determined
Kinematic viscosity	not applicable
Relative vapour density	not applicable
Evaporation speed	not applicable
Melting point [°C]	not determined
Auto-ignition temperature	not applicable
Decomposition temperature [°C]	not determined
Particle characteristics	not applicable

**9.2 Other information**

none

**SECTION 10: Stability and reactivity****10.1 Reactivity**

No dangerous reactions known if used as directed.

**10.2 Chemical stability**

The product is stable under standard conditions.

**10.3 Possibility of hazardous reactions**

Reactions with alkalis (lyes).

**10.4 Conditions to avoid**

No dangerous reactions known if used as directed.

**10.5 Incompatible materials**

Alkalies

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**10.6 Hazardous decomposition products**

No hazardous decomposition products known.

**SECTION 11: Toxicological information**
**11.1 Information on toxicological effects**
**Acute oral toxicity**

Product
ATE-mix, oral, > 2000 mg/kg
Substance
Calcium chloride dihydrate, CAS: 10035-04-8
LD50, oral, Rat, 3000 mg/kg
Acetic acid, CAS: 64-19-7
LD50, oral, Rat, 1780 mg/kg (Lit.)

**Acute dermal toxicity**

Product
ATE-mix, dermal, > 2000 mg/kg
Substance
Calcium chloride dihydrate, CAS: 10035-04-8
LD50, dermal, Rabbit, > 6500 mg/kg
Acetic acid, CAS: 64-19-7
LD50, dermal, Rabbit, 1060 mg/kg (Lit.)

**Acute inhalational toxicity**

Product
ATE-mix, inhalative (mist), > 5 mg/l 4h
Substance
Acetic acid, CAS: 64-19-7
LC50, inhalative, Rat, 11.4 mg/l 4h

**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
Acetic acid, CAS: 64-19-7
OECD 404
dermal, Rabbit
corrosive

**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
Acetic acid, CAS: 64-19-7
OECD 405
Eye, Rabbit
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
Acetic acid, CAS: 64-19-7
No information available.

**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
Acetic acid, CAS: 64-19-7
No information available.

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

Substance
Acetic acid, CAS: 64-19-7
No information available.

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

Substance
Calcium chloride dihydrate, CAS: 10035-04-8
NOAEL, oral, Rat, 169 mg/kg bw/day, no adverse effect observed
Acetic acid, CAS: 64-19-7
No information available.

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

Substance
Acetic acid, CAS: 64-19-7
No information available.

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

Substance
Acetic acid, CAS: 64-19-7
negativ
NOAEL, oral, Rat, 290 mg/kg bw/day

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

**General remarks**

Toxicological data of complete product are not available.



**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
Acetic acid, CAS: 64-19-7
LC50, (96h), Lepomis macrochirus, 75 mg/l
EC50, (24h), Daphnia magna, 47 mg/l
IC5, (16h), Scenedesmus quadricauda (alga), 4000 mg/l

**12.2 Persistence and degradability**

<b>Behaviour in environment compartments</b>	not determined
<b>Behaviour in sewage plant</b>	not determined
<b>Biological degradability</b>	not determined

**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**

No information available.

**12.7 Other adverse effects**

Do not discharge product unmonitored into the environment or into the drainage.  
Ecological data of complete product are not available.

**SECTION 13: Disposal considerations**

<b>Restrictions</b>	There are no product-specific restrictions. However, state and local disposal regulations may apply.
<b>Disposal method</b>	Disposal of this product must comply with the requirements of state and local disposal regulations.
<b>Contaminated packaging</b>	Rinse containers with water before disposal. Preferably re-cycle container, otherwise send to landfill or similar.

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**SECTION 14: Transport information****14.1 UN number or ID number**

Transport by land according to ADR/RID not applicable

Inland navigation (ADN) not applicable

Marine transport in accordance with IMDG not applicable

Air transport in accordance with IATA not applicable

Australian Code for the Transport of Dangerous Goods by Road &amp; Rail (ADG) not applicable

**14.2 UN proper shipping name**

Transport by land according to ADR/RID NO DANGEROUS GOODS

Inland navigation (ADN) NO DANGEROUS GOODS

Marine transport in accordance with IMDG NOT CLASSIFIED AS "DANGEROUS GOODS"

Air transport in accordance with IATA NOT CLASSIFIED AS "DANGEROUS GOODS"

Australian Code for the Transport of Dangerous Goods by Road &amp; Rail (ADG) not applicable

**14.3 Transport hazard class(es)**

Transport by land according to ADR/RID not applicable

Inland navigation (ADN) not applicable

Marine transport in accordance with IMDG not applicable

Air transport in accordance with IATA not applicable

Australian Code for the Transport of Dangerous Goods by Road &amp; Rail (ADG) not applicable

**14.4 Packing group**

**Transport by land according to ADR/RID** not applicable

**Inland navigation (ADN)** not applicable

**Marine transport in accordance with IMDG** not applicable

**Air transport in accordance with IATA** not applicable

**Australian Code for the Transport of Dangerous Goods by Road & Rail (ADG)** not applicable

**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

**Australian Code for the Transport of Dangerous Goods by Road & Rail (ADG)** no

**14.6 Special precautions for user**

Relevant information under SECTION 6 to 8.

**Hazchem Code** not applicable

**14.7 Maritime transport in bulk according to IMO instruments**

not applicable

**SECTION 15: Regulatory information**

**Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)** Not classified as a Scheduled Poison

**Applicable prohibitions and notifications/licensing requirements** not determined

**Agricultural and Veterinary Chemicals Act** not determined

**Listing in the Australian Inventory of Chemical Substances (AICS)** All chemical substances in this material are included on or exempted from listing on the AICS Inventory.

**Additional information** not determined

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**SECTION 16: Other information****16.1 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

**16.2 Other information****Classification procedure****Modified position**

none

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