B. Braun Avitum AG H.E.L.P. BicEl

Revision date: 01.06.2015 Revision No: 1,0

Product code: 00056-0339

1. Identification

Product identifier

H.E.L.P. BicEl

Use of the substance/mixture

Solution for extracorporeal bicarbonate plasma dialysis

Details of the supplier of the safety data sheet

Company name: B. Braun Avitum AG

Street: Schwarzenberger Weg 73 - 79

Place: D-34212 Melsungen

Responsible Department: Zentrale Service-Bereiche / Logistik und Supply Chain

Telephone: +49 (0) 5661 / 71-4422 E-Mail: logistics.service@bbraun.com

Responsible for the safety data sheet: sds@gbk-ingelheim.de

Emergency phone number: INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)

(USA domestic) 1 800 535 5053 or international (001) 352 323 3500

2. Hazard(s) identification

Classification of the chemical

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

Label elements

Additional advice on labelling

The product does not require a hazard warning label.

Hazards not otherwise classified

Not known.

3. Composition/information on ingredients

Mixtures

Chemical characterization

Aqueous solution

4. First-aid measures

Description of first aid measures

General information

Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

After inhalation

Not hazardous by inhalation.

After contact with skin

Wash hands with water as a precaution.

After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Seek medical treatment by eye specialist.

After ingestion

Rinse out mouth and give plenty of water to drink.

Consult a physician.

Most important symptoms and effects, both acute and delayed

OSHA Hazard Communication: This material is not considered hazardous by the OSHA Hazard Communication Standard 29CFR 1910.1200.

Indication of any immediate medical attention and special treatment needed

If appropriately handled and if in accordance with the general hygienic rules, no damages to health have become known.

Treat symptoms.

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5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

Product does not burn, fire-extinguishing activities according to surrounding.

Any extinguishing means and measures are acceptable.

Specific hazards arising from the chemical

Not known.

Special protective equipment and precautions for fire-fighters

No special protective equipment required.

Additional information

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

No special precautions required.

Environmental precautions

This concentrate is not allowed to be released into the sewerage, surface water or groundwater.

Methods and material for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder).

Shovel into suitable container for disposal.

Flush rests with sufficient amount of water.

Reference to other sections

Observe protective instructions (see Sections 7 and 8).

Information for disposal look up chapter 13.

7. Handling and storage

Precautions for safe handling

Advice on safe handling

Avoid contact with eyes.

Advice on protection against fire and explosion

No special protective measures against fire required.

Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Keep tightly closed.

Advice on storage compatibility

Incompatible with acids.

Specific end use(s)

Solution for extracorporeal bicarbonate plasma dialysis

8. Exposure controls/personal protection

Control parameters

Exposure controls

Protective and hygiene measures

When using do not eat, drink or smoke.

Avoid contact with eyes.

Wash hands before breaks and at the end of workday.

Take off immediately all contaminated clothing.

Eye/face protection

Safety goggles with side protection.

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Hand protection

Protective gloves resistant to chemicals made off natural-rubber latex, Minimum coat thickness 0.6 mm, Permeation resistance (wear duration) approx. 480 minutes, i.e. protective glove <Lapren 706> made by www.kcl.de.

This recommendation refers exclusively to the chemical compatibility and the lab test conforming to EN 374 carried out under lab conditions.

Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves.

Skin protection

Not required under normal use.

Respiratory protection

No personal respiratory protective equipment normally required.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: Liquid
Color: Colourless
Odor: Odorless

pH-Value (at 20 °C): 7,0 - 8,0

Changes in the physical state

Initial boiling point and boiling range: > 100 °C Flash point: n.a.

Lower explosion limits: n.a.

Ignition temperature: n.a.

Vapor pressure: n.d.

Density (at 20 °C): approx. 1,0 g/cm³

Water solubility: Completely miscible OECD 116

(at 20 °C)

Other information No data available.

10. Stability and reactivity

Reactivity

No decomposition if stored and applied as directed.

Chemical stability

Stability: Stable

Stable under normal conditions.

Possibility of hazardous reactions

Hazardous reactions: Will not occur

No hazardous reactions known.

Conditions to avoid

Not known.

Incompatible materials

No materials to be especially mentioned.

Hazardous decomposition products

No hazardous decomposition products known.

11. Toxicological information

Information on toxicological effects

Route(s) of Entry

Skin and eye contact, inhalation and ingestion.

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Acute toxicity

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

No toxicological data available.

Irritation and corrosivity

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

Sensitizing effects

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

Specific target organ toxicity (STOT) - single exposure

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

Severe effects after repeated or prolonged exposure

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

Carcinogenic/mutagenic/toxic effects for reproduction

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

Carcinogenicity (NTP): Not listed
Carcinogenicity (IARC): Not listed
Carcinogenicity (OSHA): Not listed

Aspiration hazard

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

Additional information on tests

This product is classified in accordance with the GHS regulations.

Practical experience

Other observations

If appropriately handled and if in accordance with the general hygienic rules, no damages to health have become known.

12. Ecological information

Ecotoxicity

Ecological data are not available.

Persistence and degradability

No data available.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Other adverse effects

Slightly water hazardous.

Further information

If handled and used properly, no adverse ecological effects are to be expected.

13. Disposal considerations

Waste treatment methods

Advice on disposal

Can be landfilled or incinerated, when in compliance with local regulations.

Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal.

Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.

Packaging that cannot be cleaned should be disposed of like the product.

14. Transport information

US DOT 49 CFR 172.101; Marine transport (IMDG); Air transport (ICAO-TI/IATA-DGR):

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UN number:

Non hazardous material as defined by the transport regulations.

UN proper shipping name:

Non hazardous material as defined by the transport regulations.

Transport hazard class(es):

Non hazardous material as defined by the transport regulations.

Packing group:

Non hazardous material as defined by the transport regulations.

Environmental hazards

Non hazardous material as defined by the transport regulations.

Special precautions for user

Non hazardous material as defined by the transport regulations.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Non hazardous material as defined by the transport regulations.

15. Regulatory information

U.S. Regulations

National Inventory TSCA

All of the components are listed on the TSCA inventory.

State Regulations

Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65, State of California)

This product contains no chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.

16. Other information

Hazardous Materials Information Label (HMIS)

Health: 0
Flammability: 0
Physical Hazard: 0

NFPA Hazard Ratings

Health: 0
Flammability: 0
Reactivity: 0

Unique Hazard:

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Abbreviations and acronyms

IMDG = International Maritime Code for Dangerous Goods

ernational Air Transport Association / International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

DOT = Department of Transportation

TDG = Transport of Dangerous Goods

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

CAS = Chemical Abstract Service

ISO = International Organization for Standardization

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

Other data

The information in this document is based on the present state of knowledge and is applicable to the product with regard to appropriate safety precautions.

The information describes exclusively the safety requirements for the product (s) and is based on the present level of our knowledge.



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The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

(n.a. = not applicable; n.d. = not determined)

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

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