SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sodium Chloride Infusion BP 0.9%, as Steriflex No. 1 or **free***flex*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Steriflex No. 1 has the following composition:
Sodium Chloride for Injections 0.9% w/v

3. PHARMACEUTICAL FORM

Intravenous infusion.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Steriflex No 1 is used in the treatment of dehydration to correct water and electrolyte depletion.

The smaller volume containers may be used as a diluent and delivery system when administering compatible additives so as to avoid the risk of any over dilution of the additive drug.

For intravenous infusion.

4.2. Posology and method of administration

Adults and children
The rate of administration and volume infused will depend upon the requirements of the individual patient and the judgement of the physician.

Elderly
Care should be taken to avoid circulatory overload, particularly in patients with cardiac and renal insufficiency.

Intravenous infusion.
The smaller volume containers may be used as a diluent and delivery system when administering compatible drug additives so as to avoid the risk of any over dilution of the additive drug.

TERUMOBCT

Material Safety Data Sheet

1. Identification

Commercial Name	Sodium Chloride Solution
Supplier	Terumo BCT Ltd.
Telephone	+44 (0) 28 2827 3631
Types Of Use	Infusion Solution

2. Composition

Chemical Name(s)	Sodium Chloride, Water for Injections
C.A.S. Number(s)	7647-14-5

3. Identification of Hazard

Specific Risks	N/A - Generally harmless

4. First Aid Procedures

Skin Contact	Rinse with water
Eye Contact	Rinse immediately with lots of water while eyelids are open
Ingestion	After swallowing large amounts, induce vomiting and consult physician
Inhalation	N/A

5. Fire Fighting Protection Procedures

Exposure Hazards	Not flammable

6. Accidental Release Procedures

Personal Protection	Wear gloves and eye protection
Environmental Protection	Not considered harmful to the environment
Cleanup Procedure	If local regulations permit, mop up with plenty of water and run to waste, diluting greatly with running water. Otherwise contain with sand and transfer to salvage container. Arrange removal by disposal company

7. Handling & Storage

Precautions During Handling	Wear gloves and eye protection. Wash hands before and after contact.
Storage Conditions	Store at room temperature ($25^{O}C$). Avoid excessive heat. Protect from freezing.
Hazardous Reactions	Conc. Sulphuric acid can produce hydrogen chloride

8. Exposure Control / Personal Protection

Personal Protection	Wear gloves and eye protection. Wash hands after contact.
Exposure Limits	None assigned

9. Physical & Chemical Properties

Chemical Formula	NaCl
Physical State	Liquid
pH	4.0 to 6.0
Flammability	Non-flammable

CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH REGULATIONS 1989

GENERAL SAFETY DATA SHEET FOR FRESENIUS KABI LTD INFUSION AND IRRIGATION SOLUTIONS

PRODUCT NAME:

FRESENIUS KABI LIMITED sterile pharmaceutical solutions as annexed.

MANUFACTURER: (Marketing Authorisation Holder)

Fresenius Kabi Ltd
Melbury Park
Birchwood
Warrington
Cheshire
WA3 6FF

Telephone number for technical information: 01928 594285

USES:

The usage of the above licensed pharmaceutical products is restricted by the Medicines Act 1968 to certain health care professionals and individual product usage is defined in the appropriate Pharmaceutical Data sheets available to Medical Practitioners.

COMPOSITION:

Summary compositions and principal ingredients are given in the attached tables.

PHYSICAL AND CHEMICAL PROPERTIES:

The products are clear solutions of electrolytes, e.g. salt and/or sugars and/or amino acids in water and are contained in plastic containers (except where otherwise specified). Thus their physical and chemical properties resemble those of water.

FIRE HAZARDS:

The annexed solutions are non-flammable and are not explosive.

In the case of fire, use extinguishing media appropriate for the surrounding materials. Thermal decomposition of the solutions may release water vapour and oxides of carbon. Thermal decomposition of the plastic containers may release noxious gases such as CO_2, CO, HCl or chlorinated carbons.
Heat build up may cause container rupture and spillage of contents.

HEALTH HAZARD DATA:

The annexed Fresenius Kabi Ltd products are sterile non-pyrogenic solutions intended to be administered on the direction of an appropriate health care professional, the majority can only be supplied on the prescription of a medical practitioner. The containers are single-dose containers.

Due to the special design of the containers, it is not anticipated that employees will be exposed to these solutions during their handling or administration, and thus chronic exposure of employees to these products is extremely unlikely. Accidental exposure to these products is not considered a health hazard.

EYE AND SKIN CONTACT:

Concentrated solutions of electrolytes and glucose may cause irritation and general discomfort.

INHALATION:

The product presentations make accidental exposure by this route extremely unlikely. Inhalation of the active ingredients of these solutions may product irritation and general discomfort.

INGESTION:

The product presentations make accidental exposure by this route extremely unlikely. However, ingestion of strong electrolyte solutions, particularly saline, may be irritating or emetic.

AS WITH ALL MEDICINES, STORE AWAY FROM CHILDREN

EMERGENCY FIRST AID PROCEDURES:

In the case of skin contact, wash with soap and water.
In the case of eye contact, flush eyes with plenty of water for at least 15 minutes or use a proprietary eyewash preparation; make sure to hold the eye lids open.

In case of ingestion no immediate action is necessary but seek medical advice

PRECAUTIONS FOR SAFE HANDLING, TRANSPORT AND USE:

No special precautions are necessary for safe handling or transport. Cases of these products weigh approximately 10 – 15kg.

ALL MEDICINES SHOULD BE STORED AWAY FROM CHILDREN.

Store in a cool dry place designed to store pharmaceuticals.
Containers may be damaged by freezing, avoid storing below 2°C.

Use only under medical supervision. See pack inserts and pharmaceutical data sheets. Unnecessary contact with all medicines should be avoided. When making additions to the container using a syringe, care against accidental punctures should be taken.

SPILL LEAKAGE PROCEDURES:

In the case of leaks or spillages, promptly clean up the spill with paper towels or other absorbent materials. Place the spillage and waste materials into a suitable container for disposal. Where containers are of glass appropriate precautions should be taken for handling broken glass.

Dispose of waste in accordance with local regulations for non-toxic waste.

DISPOSAL:

Empty plastic containers should be incinerated under conditions suitable for polythene of PVC materials.

WARNING – FOLLOWING MEDICAL USE, THE PRODUCT AND ADMINISTRATION EQUIPMENT COULD BE CONTAMINATED WITH HUMAN BODY FLUIDS e.g. BLOOD.

Should such a biohazard be suspected then disposal should then be as for contaminated waste, following DoH/NHS guidelines.

ADDITIONAL INFORMATION:

The supply and use of these products is controlled by the Medicines Act 1968. Further details are available to medical practitioners and pharmacists on request.

ANNEX 1

Intravenous Infusion Solutions (in plastic containers, unless otherwise stated).

Product	Constituents	PL Number	Re-order number	Size (ml)
Steriflex® No 1	Sodium Chloride Intravenous Infusion BP 0.9%	8828/0084	15-98-643 22-88-516 22-88-532 16-51-935 22-95-121 22-95-172 } PVC	50 100 250 330 500 1000
			15-98-643E 22-88-516E 22-88-532E 22-95-121E 22-95-172E } Freeflex® Polyolefine	50 100 250 500 1000
Steriflex® No 2	Sodium Chloride Intravenous Infusion BP 0.45%	8828/0036	22-88-257	500
Steriflex® No 3	Sodium Chloride 0.9% and Glucose 5% Intravenous Infusion BP	8828/0088	22-95-237 22-95-482	500 1000
Steriflex® No 6	Glucose Intravenous Infusion BP 5%	8828/0095	15-98-759 22-88-559 22-88-575 22-95-148 22-95-180 } PVC	50 100 250 500 1000
			15-98-759E 22-88-559E 22-88-575E 22-95-148E 22-95-180E } Freeflex® Polyolefine	50 100 250 500 1000
Steriflex® No 7	Glucose Intravenous Infusion BP 10%	8828/0096	22-95-245 22-95-490	500 1000
Steriflex® No 9	Ringer's Solution for Injection BPC	8828/0063	22-95-393 22-95-504	500 1000
Steriflex® No 11	Hartmann's Solution for Injection BP	8828/0083	22-95-156 22-95-199 } PVC	500 1000
			24-43-521 27-43-531 } Freeflex® Polyolefine	500 1000
Steriflex® No 12	Potassium Chloride 0.15% and Sodium Chloride 0.9% Intravenous BP	8828/0065	22-88-273 22-88-303	500 1000
Steriflex® No 13	Potassium Chloride 0.15% and Glucose 5% Intravenous Infusion BP	8828/0074	22-88-311 22-88-338	500 1000
Steriflex® No 14	Potassium Chloride 0.15% Sodium Chloride 0.18% and Glucose 4% Intravenous Infusion BP	8828/0076	22-88-346 22-88-345	500 1000
Steriflex® No 15	Potassium Chloride 0.3% and Sodium Chloride 0.9% Intravenous Infusion BP	8828/0079	22-88-362 22-88-370	500 1000

Product	Constituents	PL Number	Re-order number	Size (ml)
Steriflex® No 16	Potassium Chloride 0.3% and Glucose 5% Intravenous Infusion BP	8828/0078	22-88-389 22-88-397	500 1000
Steriflex® No 17	Potassium Chloride 0.3% Sodium Chloride 0.18% and Glucose 4% Intravenous Infusion BP	8828/0072	22-88-400 } PVC 22-88-419 } K588521 } Freeflex® Polyolefine K588531 }	500 1000 500 1000
Steriflex® No 18	Sodium Chloride 0.18% and Glucose 4% Intravenous Infusion BP	8828/0069	22-95-164 22-95-229	500 1000
Steriflex® No 19	Sodium Chloride 0.18% and Glucose 10% Intravenous Infusion BP	8828/0019	23-62-546	500
Steriflex® No 25	Lignocaine Hydrochloride 0.1% and Glucose 5% Intravenous Infusion	8828/0090	22-88-427	500
Steriflex® No 26	Lignocaine Hydrochloride 0.2% and Glucose 5% Intravenous Infusion	8828/0081	22-88-435	500
Steriflex® No 27	Lignocaine Hydrochloride 0.4% and Glucose 5% Intravenous Infusion	8828/0082	22-99-348	500
Steriflex® No 28	Potassium Chloride 0.2% and Sodium Chloride 0.9% Intravenous Infusion BP	8828/0037	23-03-531 23-03-760	500 1000
Steriflex® No 29	Potassium Chloride 0.2% and Glucose 5% Intravenous Infusion BP	8828/0027	23-03-566 23-03-795	500 1000
Steriflex® No 30	Potassium Chloride 0.2% Sodium Chloride 0.18% and Glucose 4% Intravenous Infusion	8828/0026	23-03-736 23-03-949	500 1000
Steriflex® No 31	Glucose Intravenous Infusion BP 20%	8828/0029	22-88-443	500
Steriflex® No 33	Glucose Intravenous Infusion BP 40%	8828/0030	22-88-451	500
Steriflex® No 34	Glucose Intravenous Infusion BP 50%	8828/0031	22-88-478	500
Steriflex® No 42	Glucose 5% in half-strength Hartmann's Solution	8828/0089	23-03-981	500
Steriflex® No 45	Sodium Chloride 0.45% and Glucose 5% Intravenous Infusion BP	8828/0028	23-12-999	500
Polyfusor AB	Paediatric Electrolyte	8828/0039	23-20-649	500
Polyfusor B	Sodium Bicarbonate Intravenous Infusion BP 8.4%	8828/0043	23-16-234	200
Polyfusor BC	Sodium Bicarbonate Intravenous Infusion BP 1.26%	8828/0013	23-20-800	500
Polyfusor BD	Sodium Bicarbonate Intravenous Infusion BP 1.4%	8828/0011	23-20-819	500
Polyfusor BE	Sodium Bicarbonate Intravenous Infusion BP 4.2%	8828/0042	23-20-827	500
Polyfusor C	Ringer's Solution	8828/0046	22-70-625	500

Product	Constituents	PL Number	Re-order number	Size (ml)
Polyfusor D	Glucose Intravenous Infusion BP 5%	8828/0056	22-66-830 22-66-849	500 1000
Polyfusor DB	Glucose Intravenous Infusion BP 20%	8828/0008	23-20-681	500
Polyfusor DC	Glucose Intravenous Infusion BP 40%	8828/0014	23-20-703	500
Polyfusor DE	Glucose Intravenous Infusion BP 50%	8828/0040	23-20-711	500
Polyfusor H	Hartmann's Infusion	8828/0045	22-67-055 22-73-349	500 1000
Polyfusor K	Mannitol Intravenous Infusion BP 10%	8828/0033	22-75-341	500
Polyfusor LE	Lignocaine Hydrochloride 0.2% in Glucose 5% Intravenous Infusion	8828/0094	23-23-753	500
Polyfusor LG	Lignocaine Hydrochloride 0.4% in Glucose 5% Intravenous Infusion	8828/0093	23-32-167	500
Polyfusor M	Mannitol Intravenous Infusion BP 20%	8828/0023	22-75-120	500
Polyfusor NA	Phosphates	8828/0061	23-23-761	500
Polyfusor O	Sodium Chloride Intravenous BP 0.18%	8828/0022	22-73-357	500
Polyfusor R	Glucose Intravenous Infusion BP 10%	8828/0015	22-52-309	500
Polyfusor S	Sodium Chloride Intravenous Infusion BP 0.9%	8828/0034	22-66-520 22-88-000	500 1000
Polyfusor SB	Sodium Chloride Intravenous Infusion BP 0.45%	8828/0018	23-20-843	500
Polyfusor SC	Sodium Chloride Intravenous Infusion BP 1.8%	8828/0053	23-20-894	500
Polyfusor SD	Sodium Chloride Intravenous BP 2.7%	8828/0052	23-20-908	500
Polyfusor SE	Sodium Chloride Intravenous BP 5%	8828/0051	23-20-924	500
Polyfusor SF	Glycerol 10% with Sodium Chloride Intravenous Infusion 0.9%	8828/0055	22-80-965	500
Polyfusor T	Sodium Chloride 0.18% Glucose 4% Intravenous Infusion BP	8828/0067	22-66-466	500
Polyfusor TA	Sodium Chloride 0.45% Glucose 2.5% Intravenous Infusion BP	8828/0009	23-20-568	500
Polyfusor V	Sodium Bicarbonate Intravenous Infusion BP 2.74%	8828/0012	22-94-613	500
Polyfusor W	Water for Injections	8828/0047	22-96-985 22-99-313	500 1000

Irrigation Solutions

Product	Constituents	PL Number	Re-order number	Size (ml)
Flowfusor	Sterile Water for Irrigation		22-83-174 22-83-182	1000 2000
Flowfusor	Sodium Chloride for Irrigation 0.9%		22-83-190 22-83-204	1000 2000
Flowfusor	1.5% Glycine (Amino Acetic Acid) for Irrigation		31-58-001 22-83-247	1000 2000
Flowfusor	1.5% Glycine (Amino Acetic Acid) with 1% Ethanol for Irrigation		31-17-162	2000
Flowfusor	5% Mannitol for Irrigation		77-55-910	2000
Flowfusor	Ringers for Irrigation		30-33-225	2000
Flowfusor	Purosole (2.7% Sorbitol with 0.54%) Mannitol for Irrigation		22-83-250	2000
Flowfusor	0.9% Sodium Chloride for Irrigation Bellows Pack		B312443	120
Pour Bottle	Sterile Water for Irrigation		31-58-589	1000
Pour Bottle	0.9% Sodium Chloride for Irrigation		31-58-736	1000
Flachtbehalter	Sterile Water for Irrigation		30-29-256	10000

10. **Stability & Reactivity**

Product Stability	Suitable for at least 2 years.
Hazardous Reactions	Conc. Sulphuric acid can produce hydrogen chloride
Hazardous Decomposition Products	No decomposition if stored normally

11. **Toxicological Information**

No toxic effects are to be expected when properly handled

12. **Ecological Information**

If handled properly, disturbances of the environment will not occur

13. **Waste Disposal**

Disposal Of Residue	Dispose to an appropriate, authorised disposal site
Disposal Of Packaging	After being thoroughly cleaned, empty packages may be recycled

14. **Transport Regulations**

Not dangerous according to transport regulations

15. **Regulatory Information**

N/A

16. **Special Information**

N/A

Legal Disclaimer

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide.

Terumo BCT Ltd. shall not be held liable for any damage resulting from handling or from contact with the above product.

This sheet does not exempt the user knowing and applying the regulations concerning his activity. He will have the sole responsibility regarding the use of the product as well as the precautions linked to its use.

This sheet cannot be considered to be exhaustive and does not exempt the user finding out about other regulations which might apply to the storage and handling of the product for which he is solely responsible.

4.3. Contraindications

Patients with sodium overload. It is well known that this may occur with myocardial and renal damage, but it should also be appreciated that in that in the first five or six days after surgery or severe trauma, there may be an inability to excrete unwanted sodium.

4.4. Special warnings and special precautions for use

This product is not suitable for protracted use unless there is heavy continued loss of electrolyte, even then it should be used with care. Saline solutions should not be administered rapidly or for prolonged periods particularly in infants and the elderly. In potassium deficient patients administration of normal saline will increase potassium loss so that if it is given, potassium supplements should also be given.

The physician should also be alerted to the possibility of adverse reactions to drug additives diluted and administered in this container. Prescribing information for drug additives to be administered in this manner should be consulted.

The label states: Do not use unless the solution is clear and free from particles.

4.5. Interactions with other medicinal products and other forms of Interaction

No clinically significant interactions.

4.6. Pregnancy and lactation

The safety of this solution during pregnancy and lactation has not been assessed, but its use during these periods is not considered to constitute a hazard.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Thrombosis of the chosen vein is always a possibility with intravenous infusion. If infusion is protracted then another vein should be selected after 12-24 hours.

4.9. Overdose

Overdosage may lead to fluid overload and electrolyte imbalance. Treatment should consist of discontinuing the infusion and if necessary administering a duiretic.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Sodium chloride provides a source of sodium and chloride ions to maintain the osmotic tension of the extracellular fluid and tissues.

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Name Specification	%w/v
Water for Injections in bulk BP	To 100
Hydrochloric Acid BP	QS
Sodium Hydroxide BP	QS

6.2. Incompatibilities

Incompatible with Amiodarone, Amphotericin B, Amsacrine and sodium nitroprusside.

Because of the nature of the plastic material of the Steriflex bag (PVC) this solution should not be used as a vehicle for the administration of drugs which may be sorbed on to the bag to varying and significant degrees.

6.3. Shelf life

50, 100, 150 & 250ml PVC Bags - 18 months.
330, 500 & 1000ml PVC Bags – 24 months.
50, 100 & 150ml Polyolefin Bags – 24 months
250, 330, 500 & 1000ml Polyolefin bags – 36 months

6.4. Special precautions for storage

Store between 2 and 25°C

6.5. Nature and contents of container

The container is 50, 100, 150, 250, 330, 500 or 1000ml flexible bag made of medical grade PVC.

a) A hermetically sealed polythene bag.
b) A rectangular pouch consisting of polyamide/polythene composite
c) Polyamide/Polyethylene-Propylene composite laminate welded to polypropylene ethylene propylene composite, plugged with a polycarbonate plug with either a bromobutyl (West 4481/45) or gum (West 7006/45) stopper.

Or

A flexible 50, 100, 150, 250, 330, 500 or 1000ml polyolefine bag sealed in a polyolefine overwrap.

6.6. Instruction for use and handling

Opening the overwrap:

Locate the corner tabs at the end of the bag. Grip the two tabs and pull the two halves of the overwrap apart, releasing the bag onto a clean surface.

Setting up the solution:

Position the roller clamp of the giving-set to just below the drip chamber and close. Hold the base of the giving set port firmly and grip the wings of the twist of tab. Twist to remove the protective cover. Still holding the base of the giving-set port push the set spike fully into the port to ensure a leak proof connection. Prime the set in accordance with the manufacturer's instructions.

7. MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
Cestrian Court
Eastgate Way
Manor Park
Runcorn
Cheshire
WA7 1NT
UK

8. MARKETING AUTHORISATION NUMBER

PL 08828/0084.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

27 July 1989/03 February 1999

10. DATE OF REVISION OF THE TEXT

August 2006