

Issuing Date: 24-Jul-2018

Revision Date: 28-Aug-2020

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**Product identifier****SDS Number:**

BXU527117

Product Name:

CLINIMIX and CLINIMIX E Injection - Amino Acid Solution

Other means of identification**Product Code(s):**

2B7735, 2B7737, 2B7716, 2B7726, 2B7704, 2B7738, 2B7717, 2B7727, 2B7705, 2B7740, 2B7721, 2B7730, 2B7741, 2B7722, 2B7731, 2B7709, 2B7710, EADB9913, EADB9933, EADB9935, EADB9953, EADB9955, EADB9943, EADB9945, EADB9963, EADB9965, NDC 0338-1142-03, NDC 0338-1144-03, NDC 0338-1113-04, NDC 0338-1145-03, NDC 0338-1115-04, NDC 0338-1147-03, NDC 0338-1123-04, NDC 0338-1148-03, NDC 0338-1125-04, NDC 0338-0210-06, NDC 0338-0214-04, NDC 0338-0202-06, NDC 0338-0206-04, NDC 0338-1133-03, NDC 0338-1089-04, NDC 0338-1134-03, NDC 0338-1091-04, NDC 0338-1137-03, NDC 0338-1099-04, NDC 0338-1138-03, NDC 0338-1101-04, NDC 0338-0198-06, NDC 0338-0188-06, NDC 0338-0194-04, NDC 0338-0180-06, NDC 0338-0184-04

Synonyms:

CLINIMIX 4.25/5 sulfite-free(4.25% Amino Acid in 5% Dextrose) Injection
CLINIMIX 4.25/10 sulfite-free(4.25% Amino Acid in 10% Dextrose) Injection
CLINIMIX 5/15 sulfite-free(5% Amino Acid in 15% Dextrose) Injection
CLINIMIX 5/20 sulfite-free(5% Amino Acid in 20% Dextrose) Injection
CLINIMIX 6/5 sulfite-free(6% Amino Acid in 5% Dextrose) Injection
CLINIMIX 8/10 sulfite-free(8% Amino Acid in 10% Dextrose) Injection
CLINIMIX 8/14 sulfite-free(8% Amino Acid in 14% Dextrose) Injection
CLINIMIX E 2.75/5 sulfite-free (2.75% Amino Acid with Electrolytes in 5% Dextrose with Calcium) Injection
CLINIMIX E 4.25/5 sulfite-free (4.25% Amino Acid with Electrolytes in 5% Dextrose with Calcium) Injection
CLINIMIX E 4.25/10 sulfite-free (4.25% Amino Acid with Electrolytes in 10% Dextrose with Calcium) Injection
CLINIMIX E 5/15 sulfite-free (5% Amino Acid with Electrolytes in 15% Dextrose with Calcium) Injection
CLINIMIX E 5/20 sulfite-free (5% Amino Acid with Electrolytes in 20% Dextrose with Calcium) Injection
CLINIMIX E 8/10 sulfite-free(8% Amino Acid with Electrolytes in 10% Dextrose with Calcium) Injection
CLINIMIX E 8/14 sulfite-free(8% Amino Acid with Electrolytes in 14% Dextrose with Calcium) Injection

Recommended use of the chemical and restrictions on use**Product Use:**

Pharmaceutical.

Product Type:

Regulated Prescription Drug

Uses advised against

No information available

Details of the supplier of the safety data sheet

BAXTER HEALTHCARE CORPORATION

1 BAXTER PARKWAY

DEERFIELD, ILLINOIS 60015

US: (800) 933-0303

Canada: (855)-584-1368

Emergency telephone number

Rocky Mountain Poison and Drug Safety: USA (888) 990-0996

OUTSIDE USA (303) 389-1422

CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. HAZARDS IDENTIFICATION**Classification**

OSHA Regulatory Status

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label Elements**Emergency Overview**

The product contains no substances which at their given concentration, are considered to be hazardous to health

Hazards not otherwise classified (HNOC)**Other Information**

Unknown Acute Toxicity

5.32 % of the mixture consists of ingredient(s) of unknown toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Weight-%
Alanine	56-41-7	1-3
Arginine	74-79-3	1-3
Glycine	56-40-6	1-3
Leucine	61-90-5	<1
Proline	147-85-3	<1
Isoleucine	73-32-5	<1
Valine	72-18-4	<1
Lysine	56-87-1	<1
Serine	56-45-1	<1
Phenylalanine	63-91-2	<1
Histidine	71-00-1	<1
Threonine	72-19-5	<1
Tryptophan	73-22-3	<1
Methionine	63-68-3	<1
Tyrosine	60-18-4	<0.1
Sodium Acetate Trihydrate	6131-90-4	0-<1
POTASSIUM PHOSPHATE DIBASIC	7758-11-4	0-<1
Magnesium chloride, hexahydrate	7791-18-6	0-<1
Sodium Chloride	7647-14-5	0-<1
Water	7732-18-5	>86

4. FIRST AID MEASURES**Description of first aid measures****General Advice**

Treat symptomatically and supportively.

Eye contact:

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

Skin contact:

In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms occur.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed

No information available.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards arising from the chemical

No information available.

Special protective equipment for firefighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions

See Section 12 for environmental precautions.

Methods and material for containment and cleaning up

Methods for Containment:

If emergency personnel are unavailable, contain spilled material.

Methods for cleaning up:

For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical measures/precautions: Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature 25 °C (77 °F). Avoid excessive heat. Do not freeze.

Incompatible materials: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Exposure Limits: This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical name	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Alanine 56-41-7	None	None	None	None	None	None
Arginine 74-79-3	None	None	None	None	None	None
Glycine 56-40-6	None	None	None	None	None	None
Leucine 61-90-5	None	None	None	None	None	None
Proline 147-85-3	None	None	None	None	None	None
Isoleucine 73-32-5	None	None	None	None	None	None
Valine 72-18-4	None	None	None	None	None	None
Lysine 56-87-1	None	None	None	None	None	None
Serine 56-45-1	None	None	None	None	None	None
Phenylalanine 63-91-2	None	None	None	None	None	None
Histidine 71-00-1	None	None	None	None	None	None
Threonine 72-19-5	None	None	None	None	None	None
Tryptophan 73-22-3	None	None	None	None	None	None
Methionine 63-68-3	None	None	None	None	None	None
Tyrosine 60-18-4	None	None	None	None	None	None
Sodium Acetate Trihydrate 6131-90-4	None	None	None	None	None	None
POTASSIUM PHOSPHATE DIBASIC 7758-11-4	None	None	None	None	None	None
Magnesium chloride, hexahydrate 7791-18-6	None	None	None	None	None	None
Sodium Chloride 7647-14-5	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Appropriate engineering controls

Engineering Measures

No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Individual protection measures, such as personal protective equipment

Eye protection

Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

Hand protection

Use chemical resistant, impervious gloves.

Skin and body protection Work uniform or laboratory coat.

Respiratory protection No personal respiratory protective equipment normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Liquid
Appearance:	Aqueous solution.
Color:	Clear, colorless to light yellow.
Odor:	No information available
Odor Threshold:	No information available
pH:	No information available
Melting point / melting range:	No information available
Boiling point / boiling range:	No information available
Flash point:	No information available
Evaporation rate:	No information available
Flammability (solid, gas):	No information available
Flammable limits	No information available
in air-upper (%):	
Flammable limits	No information available
in air-lower (%):	
Vapor pressure:	No information available
Vapor density	No information available
Density:	No information available
Solubility:	Soluble in water.
Partition coefficient	No information available
(n-octanol/water):	
Autoignition temperature:	No information available
Decomposition temperature	No information available
Viscosity:	No information available
Explosive Properties:	No information available
Oxidizing Properties:	No information available

Other information

10. STABILITY AND REACTIVITY

Reactivity

No data available

Chemical stability

Stable under recommended storage conditions

Possibility of hazardous reactions

None under normal use conditions

Conditions to Avoid

Avoid excessive heat. Do not freeze.

Incompatible materials

None known

Hazardous decomposition products

No data available

11. TOXICOLOGICAL INFORMATION

Chemical name	Inhalation LC50	Dermal LD50	Oral LD50
Alanine 56-41-7	-	-	-
Arginine 74-79-3	-	-	-
Glycine 56-40-6	-	-	= 7930 mg/kg (Rat)
Leucine 61-90-5	-	-	-
Proline 147-85-3	-	-	-
Isoleucine 73-32-5	-	-	-
Valine 72-18-4	-	-	-
Lysine 56-87-1	-	-	-
Serine 56-45-1	-	-	-
Phenylalanine 63-91-2	-	-	-
Histidine 71-00-1	-	-	> 15 g/kg (Rat)
Threonine 72-19-5	-	-	-
Tryptophan 73-22-3	-	-	> 16 g/kg (Rat)
Methionine 63-68-3	-	-	= 36 g/kg (Rat)
Tyrosine 60-18-4	-	-	-
Sodium Acetate Trihydrate 6131-90-4	-	-	-
POTASSIUM PHOSPHATE DIBASIC 7758-11-4	-	-	-
Magnesium chloride, hexahydrate 7791-18-6	-	-	= 8100 mg/kg (Rat)
Sodium Chloride 7647-14-5	42 g/m ³ 1 h (Rat)	> 10 g/kg (Rabbit)	= 3 g/kg (Rat)
Water 7732-18-5	-	-	> 90 mL/kg (Rat)

Information on likely routes of exposure

Inhalation:	Inhalation not likely under normal use conditions.
Eye contact:	Not expected to cause eye irritation.
Skin contact:	Not expected to cause skin irritation.
Ingestion:	Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Gastrointestinal effects (may include nausea, upset stomach, loss of appetite). Metabolic complications (may include metabolic acidosis, electrolyte imbalances, dehydration, increased glucose levels, decrease phosphate levels, increased urination, elevated liver enzymes, increased ammonia levels).

Information on Toxicological Effects

Symptoms: No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation: Not classified.

Corrosivity: Not classified.

Sensitization: Not classified.

Mutagenic effects: Not classified.

Carcinogenic effects: Not classified.

Chemical name	ACGIH	IARC	NTP	OSHA
Alanine 56-41-7	-	-	-	-
Arginine 74-79-3	-	-	-	-
Glycine 56-40-6	-	-	-	-
Leucine 61-90-5	-	-	-	-
Proline 147-85-3	-	-	-	-
Isoleucine 73-32-5	-	-	-	-
Valine 72-18-4	-	-	-	-
Lysine 56-87-1	-	-	-	-
Serine 56-45-1	-	-	-	-
Phenylalanine 63-91-2	-	-	-	-
Histidine 71-00-1	-	-	-	-
Threonine 72-19-5	-	-	-	-
Tryptophan 73-22-3	-	-	-	-
Methionine 63-68-3	-	-	-	-
Tyrosine 60-18-4	-	-	-	-
Sodium Acetate Trihydrate 6131-90-4	-	-	-	-
POTASSIUM PHOSPHATE DIBASIC 7758-11-4	-	-	-	-
Magnesium chloride, hexahydrate 7791-18-6	-	-	-	-
Sodium Chloride 7647-14-5	-	-	-	-
Water 7732-18-5	-	-	-	-

Reproductive toxicity: Not classified.

STOT - single exposure: Not classified.

STOT - repeated exposure: Not classified.

Aspiration Hazard: Not classified.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity

5.32 % of the mixture consists of ingredient(s) of unknown toxicity

12. ECOLOGICAL INFORMATION

Chemical name	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Alanine 56-41-7	None.	None.	None.	None.
Arginine 74-79-3	None.	None.	None.	None.
Glycine 56-40-6	None.	None.	None.	None.
Leucine 61-90-5	None.	None.	None.	None.
Proline 147-85-3	None.	None.	None.	None.
Isoleucine 73-32-5	None.	None.	None.	None.
Valine 72-18-4	None.	None.	None.	None.
Lysine 56-87-1	None.	None.	None.	None.
Serine 56-45-1	None.	None.	None.	None.
Phenylalanine 63-91-2	None.	None.	None.	None.
Histidine 71-00-1	None.	None.	None.	None.
Threonine 72-19-5	None.	None.	None.	None.
Tryptophan 73-22-3	None.	None.	None.	None.
Methionine 63-68-3	None.	None.	None.	None.
Tyrosine 60-18-4	None.	None.	None.	None.
Sodium Acetate Trihydrate 6131-90-4	None.	None.	None.	7200mg/LEC50Pseudomonas putida18h
POTASSIUM PHOSPHATE DIBASIC 7758-11-4	None.	None.	None.	None.
Magnesium chloride, hexahydrate 7791-18-6	None.	None.	None.	None.
Sodium Chloride 7647-14-5	1000 mg/L EC50 48 h 340.7 - 469.2 mg/L EC50 48 h	4747 - 7824 mg/L LC50 Oncorhynchus mykiss 96 h 12946 mg/L LC50 Lepomis macrochirus 96 h 6020 - 7070 mg/L LC50 Pimephales promelas 96 h 6420 - 6700 mg/L	None.	None.

		LC50 Pimephales promelas 96 h 5560 - 6080 mg/L LC50 Lepomis macrochirus 96 h 7050 mg/L LC50 Pimephales promelas 96 h		
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity

No information available

13.474 % of the mixture consists of components(s) of unknown hazards to the aquatic environment

Persistence and degradability

No information available.

Bioaccumulative potential

Bioaccumulative potential

Mobility in soil

No information available

Other adverse effects

No information available

13. DISPOSAL CONSIDERATIONS**Waste treatment methods****Waste from residues/unused products**

In accordance with local and national regulations

Contaminated Packaging

In accordance with local and national regulations.

14. TRANSPORT INFORMATION**DOT**

Not regulated

15. REGULATORY INFORMATION**U.S. Regulations:****TSCA Inventory List -**

The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Chemical name	Weight-%	RCRA Status:	CERCLA Reportable	CERCLA/SARA - 302 Ext. haz.	Listed as Sara 313 title III:
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			Quantity:	substances:	
Alanine 56-41-7	1-3	Not Listed	Not Listed	Not Listed	Not Listed
Arginine 74-79-3	1-3	Not Listed	Not Listed	Not Listed	Not Listed
Glycine 56-40-6	1-3	Not Listed	Not Listed	Not Listed	Not Listed
Leucine 61-90-5	<1	Not Listed	Not Listed	Not Listed	Not Listed
Proline 147-85-3	<1	Not Listed	Not Listed	Not Listed	Not Listed
Isoleucine 73-32-5	<1	Not Listed	Not Listed	Not Listed	Not Listed
Valine 72-18-4	<1	Not Listed	Not Listed	Not Listed	Not Listed
Lysine 56-87-1	<1	Not Listed	Not Listed	Not Listed	Not Listed
Serine 56-45-1	<1	Not Listed	Not Listed	Not Listed	Not Listed
Phenylalanine 63-91-2	<1	Not Listed	Not Listed	Not Listed	Not Listed
Histidine 71-00-1	<1	Not Listed	Not Listed	Not Listed	Not Listed
Threonine 72-19-5	<1	Not Listed	Not Listed	Not Listed	Not Listed
Tryptophan 73-22-3	<1	Not Listed	Not Listed	Not Listed	Not Listed
Methionine 63-68-3	<1	Not Listed	Not Listed	Not Listed	Not Listed
Tyrosine 60-18-4	<0.1	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Acetate Trihydrate 6131-90-4	0-<1	Not Listed	Not Listed	Not Listed	Not Listed
POTASSIUM PHOSPHATE DIBASIC 7758-11-4	0-<1	Not Listed	Not Listed	Not Listed	Not Listed
Magnesium chloride, hexahydrate 7791-18-6	0-<1	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride 7647-14-5	0-<1	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	>86	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Chemical name	California Prop. 65	Minnesota Right-To -Know:	Florida Right-to-Kno w Reporting List:	Rhode Island Right-to-Kno w List:	Massachusetts Right-to-Kno w List:	Pennsylvania Right-to-Kno w:	New Jersey Right-to-Kno w:
Alanine 56-41-7	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Arginine 74-79-3	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Glycine 56-40-6	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Leucine 61-90-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Proline	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

147-85-3							
Isoleucine 73-32-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Valine 72-18-4	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Lysine 56-87-1	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Serine 56-45-1	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Phenylalanine 63-91-2	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Histidine 71-00-1	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Threonine 72-19-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Tryptophan 73-22-3	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Methionine 63-68-3	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Tyrosine 60-18-4	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Acetate Trihydrate 6131-90-4	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
POTASSIUM PHOSPHATE DIBASIC 7758-11-4	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Magnesium chloride, hexahydrate 7791-18-6	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride 7647-14-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List -

This product does not comply with DSL

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

Changes to Section 1. Change to formulation.

Additional information:

Not Available.

Prepared by:

Baxter Research & Development

Issuing Date:

24-Jul-2018

Revision Date:

28-Aug-2020

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of Safety Data Sheet