

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Trade name or designation of the mixture	Single chain Human tPA
Registration number	-
Synonyms	None.
Product code	101201
Issue date	01-December-2017
Version number	02
Revision date	26-July-2017
Supersedes date	28-May-2015

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

Identified uses	Not available.
Uses advised against	Use in accordance with supplier's recommendations.

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters BioMedica Diagnostics Inc.
94 Wentworth Road, PO Box 1030
Windsor, Nova Scotia CANADA B0N 2T0

Contact person Corporate Phone: 1-902-798-5105
Corporate Fax: 1-902-798-1025
Email: info@biomedicadiagnostics.com
Website: www.biomedicadiagnostics.com

1.4. Emergency telephone number US, Canada, Puerto Rico & Virgin Islands 1-800-255-3924
International +1-813-248-0585
Australia 1-300-954-583
Brazil 0-800-591-6042
China 400-120-0751
India 000-800-100-4086
Mexico 01-800-099-0731

Contract number MIS9591327

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Classification Xn;R22

Classification according to Regulation (EC) No 1272/2008 as amended

Health hazards
Acute toxicity, oral Category 4 H302 - Harmful if swallowed.

Hazard summary

Physical hazards Not classified for physical hazards.
Health hazards Harmful if swallowed.
Environmental hazards Not classified for hazards to the environment.
Specific hazards Avoid contact with eyes and skin. Do not ingest or inhale.
Main symptoms Dust may irritate skin and the respiratory system.

2.2. Label elements**Label according to Regulation (EC) No. 1272/2008 as amended**

Contains: Ammonium bicarbonate

Hazard pictograms



Signal word

Warning

Hazard statements

H302

Harmful if swallowed.

Precautionary statements

Prevention

P264

Wash thoroughly after handling.

P270

Do not eat, drink or smoke when using this product.

Response

P301 + P312

IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.

P330

Rinse mouth.

Storage

Store away from incompatible materials.

Disposal

Dispose of waste and residues in accordance with local authority requirements.

Supplemental label information

None.

2.3. Other hazards

Not a PBT or vPvB substance or mixture.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Ammonium bicarbonate	70 - 90	1066-33-7 213-911-5	-	-	

Classification: **DSD:** Xn;R22
 CLP: Acute Tox. 4;H302

List of abbreviations and symbols that may be used above

DSD: Directive 67/548/EEC.

CLP: Regulation No. 1272/2008.

Composition comments

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation

Move to fresh air. If breathing is difficult, give oxygen. Get medical attention if any discomfort continues.

Skin contact

For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.

Eye contact

Flush eyes thoroughly with water for at least 15 minutes. If eye irritation persists, get medical advice/attention.

Ingestion

Rinse mouth thoroughly if dust is ingested. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Dust may irritate skin and the respiratory system.

4.3. Indication of any immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards

Will burn if involved in a fire.

5.1. Extinguishing media

Suitable extinguishing media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media

None known.

5.2. Special hazards arising from the substance or mixture	Fire will generate toxic and irritating gases.
5.3. Advice for firefighters	
Special protective equipment for firefighters	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures	
For non-emergency personnel	Keep unnecessary personnel away. See Section 8 of the SDS for Personal Protective Equipment.
For emergency responders	Use personal protection recommended in Section 8 of the SDS.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Avoid dust formation. Sweep or scoop up and remove.
6.4. Reference to other sections	For waste disposal, see Section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid prolonged exposure. Wash thoroughly after handling. Avoid inhalation of dust and contact with skin and eyes. Observe good laboratory hygiene practices.
7.2. Conditions for safe storage, including any incompatibilities	Store at 2 - 8°C. Store in a closed container away from incompatible materials.
7.3. Specific end use(s)	Not available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters	
Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no-effect level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.
8.2. Exposure controls	
Appropriate engineering controls	No special ventilation requirements.
Individual protection measures, such as personal protective equipment	
General information	Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Wear dust-resistant safety goggles.
Skin protection	
- Hand protection	It is a good industrial hygiene practice to minimise skin contact. Chemical resistant gloves are recommended.
- Other	It is a good industrial hygiene practice to minimise skin contact.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practices.
Environmental exposure controls	Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties	
Appearance	Straw colored powder.
Physical state	Solid.
Form	Powder.

Colour	Straw colored.
Odour	None.
Odour threshold	Not applicable.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not relevant.
Flash point	Not relevant.
Evaporation rate	Not available.
Flammability (solid, gas)	Non flammable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not relevant.
Vapour density	Not relevant.
Relative density	Not available.
Solubility(ies)	Soluble in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not relevant.
Explosive properties	Not relevant.
Oxidizing properties	Not oxidizing.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Stable at normal conditions.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Polymerization will not occur.
10.4. Conditions to avoid	Keep away from heat.
10.5. Incompatible materials	Strong oxidising agents. Strong reducing agents. Strong acids.
10.6. Hazardous decomposition products	Carbon oxides.

SECTION 11: Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system.
Skin contact	Dust may irritate skin.
Eye contact	Dust may irritate the eyes.
Ingestion	Harmful if swallowed.

Symptoms Dust may irritate skin and the respiratory system.

11.1. Information on toxicological effects

Acute toxicity Harmful if swallowed.

Components	Species	Test results
Ammonium bicarbonate (CAS 1066-33-7)		
Acute		
<i>Oral</i>		
LD50	Rat	1470 mg/kg
Skin corrosion/irritation	Dust may irritate skin.	

Serious eye damage/eye irritation	Dust may irritate the eyes.
Respiratory sensitisation	Not classified.
Skin sensitisation	Not classified.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified.
Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Mixture versus substance information	Not available.
Other information	Not available.

SECTION 12: Ecological information

12.1. Toxicity

Components	Species	Test results
Ammonium bicarbonate (CAS 1066-33-7)		
Aquatic		
Fish	LC50 Rainbow trout, donaldson trout (Oncorhynchus mykiss)	16.1 - 18.7 mg/l, 96 hours

12.2. Persistence and degradability No data available.

12.3. Bioaccumulative potential No data available.

Partition coefficient n-octanol/water (log Kow) Not available.

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil Not available.

Mobility in general The product is soluble in water.

12.5. Results of PBT and vPvB assessment Not a PBT or vPvB substance or mixture.

12.6. Other adverse effects The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Dispose in accordance with all applicable regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006 as amended. In the European Union this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

DSD: Directive 67/548/EEC.
CLP: Regulation No. 1272/2008.
DNEL: Derived No-Effect Level.
PNEC: Predicted No-Effect Concentration.

References

ECHA CHEM

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R22 Harmful if swallowed.
H302 Harmful if swallowed.

Training information

Follow training instructions when handling this material.

Disclaimer

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall BioMedica Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if BioMedica Diagnostics has been advised of the possibility of such damages.