

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	dPT Activator, in ACTICLOT® dPT™
Registration number	-
Synonyms	None.
Product code	824, dPT Activator
Issue date	01-December-2017
Version number	02
Revision date	17-July-2017
Supersedes date	08-April-2015

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

Identified uses	The ACTICLOT® dPT™ is intended for the qualitative determination of Lupus Anticoagulants (LA) in human plasma.
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 Carc. Cat. 2;R45, Muta. Cat. 2;R46, Xn;R20/22-48/20/22, Xi;R36/37/38

The full text for all R-phrases is displayed in section 16.

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

Health hazards

Skin corrosion/irritation	Category 2	H315 - Causes skin irritation.
Serious eye damage/eye irritation	Category 2	H319 - Causes serious eye irritation.
Germ cell mutagenicity	Category 1B	H340 - May cause genetic defects.
Carcinogenicity	Category 1B	H350 - May cause cancer.
Specific target organ toxicity - single exposure	Category 3 respiratory tract irritation	H335 - May cause respiratory irritation.
Specific target organ toxicity - repeated exposure	Category 2	H373 - May cause damage to organs through prolonged or repeated exposure.

Hazard summary

Physical hazards Not classified for physical hazards.

Health hazards	May cause cancer. May cause heritable genetic damage. Also harmful by inhalation and if swallowed. Irritating to eyes, respiratory system and skin. Also harmful: danger of serious damage to health by prolonged exposure through inhalation and 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	May cause redness and pain. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

2.2. Label elements

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

Contains: Cadmium chloride

Hazard pictograms



Signal word Danger

Hazard statements

H350	May cause cancer.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H340	May cause genetic defects.
H373	May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

Prevention

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe mist or vapour.
P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P271	Use only outdoors or in a well-ventilated area.

Response

P302 + P352	IF ON SKIN: Wash with plenty of water.
P332 + P313	If skin irritation occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312	Call a POISON CENTER/doctor if you feel unwell.

Storage

P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.

Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
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Supplemental label information Restricted to professional users.

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
Tris-(hydroxymethyl)aminomethane	25 - 30	77-86-1 201-064-4	-	-	

Classification: **DSD:** Xi;R36/37/38
CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Calcium chloride	5 - 8	10043-52-4 233-140-8	-	017-013-00-2	
Classification:	DSD: Xi;R36				
	CLP: Eye Irrit. 2;H319				
Cadmium chloride	0.1 - < 0.25	7790-78-5 233-296-7	-	048-008-00-3	
Classification:	DSD: Carc. Cat. 2;R45, Muta. Cat. 2;R46, Repr. Cat. 2;R60-61, T+;R26, T;R25-48/23/25, N;R50/53				E
	CLP: Acute Tox. 3;H301, Acute Tox. 2;H330, Muta. 1B;H340, Carc. 1B;H350, Repr. 1B;H360FD, STOT RE 1;H372, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				

List of abbreviations and symbols that may be used above

DSD: Directive 67/548/EEC.

CLP: Regulation No. 1272/2008.

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

Nota E: Substances with specific effects on human health (see Chapter 4 of Annex VI) that are classified as carcinogenic, mutagenic and/or toxic for reproduction in categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn). For these substances, the risk phrases R 20, R 21, R 22, R 23, R 24, R 25, R 26, R 27, R 28, R 39, R 68 (harmful), R 48 and R 65 and all combinations of these risk phrases shall be preceded by the word "Also". Examples: R 45-23 "May cause cancer. Also toxic by inhalation"; R 46-27/28 "May cause heritable genetic damage. Also very toxic in contact with skin and if swallowed".

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. IF exposed or concerned: Get medical advice/attention.

4.1. Description of first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if irritation develops and persists.

Eye contact Flush thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth thoroughly with water. If material is ingested, immediately contact a physician or poison control centre.

4.2. Most important symptoms and effects, both acute and delayed May cause redness and pain. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

SECTION 5: Firefighting measures

General fire hazards The product is not flammable.

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 When heated to decomposition, may produce hydrazoic acid fumes.

5.3. Advice for firefighters

Special protective equipment for firefighters 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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
- For emergency responders** Use personal protection as recommended in section 8 of the SDS.

6.2. Environmental precautions Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

6.3. Methods and material for containment and cleaning up Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

6.4. Reference to other sections For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Do not handle until all safety precautions have been read and understood. Avoid dust formation. Avoid inhalation of dust and contact with skin and eyes. Wash thoroughly after handling. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities Store in a closed container away from incompatible materials. Store at 2-8°C (35-46°F).

7.3. Specific end use(s) The ACTICLOT® dPT™ is intended for the qualitative determination of Lupus Anticoagulants (LA) in human plasma.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Cadmium chloride (CAS 7790-78-5)	TWA	0.025 mg/m3

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.

Exposure guidelines Follow standard monitoring procedures.

8.2. Exposure controls

Appropriate engineering controls Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

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 approved safety glasses or goggles.

Skin protection

- Hand protection Wear appropriate chemical resistant gloves.

- Other Wear lab coat or other protective garments. Remove contaminated clothing promptly.

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

- Physical state** Solid.
- Form** Powder.

Colour	White.
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 applicable.
Flammability limit - upper (%)	Not applicable.
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 explosive.
Oxidizing properties	Not oxidizing.
9.2. Other information	
Percent volatile	Not relevant.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Hazardous polymerisation does not occur.
10.4. Conditions to avoid	Keep away from heat.
10.5. Incompatible materials	Strong oxidizers, strong acids, and strong bases.
10.6. Hazardous decomposition products	Cadmium oxides. Carbon oxides. Nitrogen oxides.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Inhalation	Dust may irritate respiratory system. Prolonged inhalation may be harmful.
Skin contact	Causes skin irritation.
Eye contact	Causes serious eye irritation.
Ingestion	May cause discomfort if swallowed.
Symptoms	Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. May cause redness and pain.

11.1. Information on toxicological effects

Acute toxicity May cause discomfort if swallowed.

Components	Species	Test results
Calcium chloride (CAS 10043-52-4)		
Acute		
<i>Oral</i>		
LD50	Rabbit	1000 mg/kg

Components	Species	Test results
Tris-(hydroxymethyl)aminomethane (CAS 77-86-1)		
Acute		
<i>Oral</i>		
LD50	Rat	5900 mg/kg
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/eye irritation	Causes serious eye irritation.	
Respiratory sensitisation	Not a respiratory sensitiser.	
Skin sensitisation	Not a skin sensitiser.	
Germ cell mutagenicity	May cause genetic defects.	
Carcinogenicity	May cause cancer.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Cadmium chloride (CAS 7790-78-5)		1 Carcinogenic to humans.
Reproductive toxicity	Not classified.	
Specific target organ toxicity - single exposure	May cause respiratory irritation.	
Specific target organ toxicity - repeated exposure	May cause damage to organs through prolonged or repeated exposure.	
Aspiration hazard	Not classified.	
Mixture versus substance information	Not available.	
Other information	No other specific acute or chronic health impact noted.	

SECTION 12: Ecological information

12.1. Toxicity	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.	
12.2. Persistence and degradability	No data is available on the degradability of this product.	
12.3. Bioaccumulative potential	Not available.	
Partition coefficient n-octanol/water (log Kow)		
Tris-(hydroxymethyl)aminomethane (CAS 77-86-1)		-2.31 (20°C)
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	Not available.	

SECTION 13: Disposal considerations

13.1. Waste treatment methods		
Residual waste	Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).	
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.	
EU waste code	Waste codes should be assigned by the user based on the application for which the product was used.	
Disposal methods/information	Dispose in accordance with all applicable regulations. This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up.	

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

Cadmium chloride (CAS 7790-78-5)

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

Cadmium chloride (CAS 7790-78-5)

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

Cadmium chloride (CAS 7790-78-5)

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

Cadmium chloride (CAS 7790-78-5)

Other EU regulations

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

Cadmium chloride (CAS 7790-78-5)

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

Cadmium chloride (CAS 7790-78-5)

Calcium chloride (CAS 10043-52-4)

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

Cadmium chloride (CAS 7790-78-5)

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. 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. Pregnant women should not work with the product, if there is the least risk of exposure. Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work.

SECTION 16: Other information

List of abbreviations

DNEL: Derived No-Effect Level.
PNEC: Predicted No-Effect Concentration.
PBT: Persistent, bioaccumulative and toxic.
vPvB: Very Persistent and very Bioaccumulative.
Not available.

References

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

R20/22 Also harmful by inhalation and if swallowed.
R25 Toxic if swallowed.
R26 Very toxic by inhalation.
R36 Irritating to eyes.
R36/37/38 Irritating to eyes, respiratory system and skin.
R45 May cause cancer.
R46 May cause heritable genetic damage.
R48/20/22 Also harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
R48/23/25 Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R60 May impair fertility.
R61 May cause harm to the unborn child.
H301 Toxic if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H330 Fatal if inhaled.
H335 May cause respiratory irritation.
H340 May cause genetic defects.
H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Training information

Follow training instructions when handling this material.

Disclaimer

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