



SAFETY DATA SHEET

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

1.1. Product identifier

| | |
|--|---------------------------|
| Trade name or designation of the mixture | BD Vacutainer® CTAD Tubes |
| Registration number | - |
| Synonyms | None. |
| Product code | 367562, 367599, 367947 |
| Issue date | 07-September-2015 |
| Version number | 01 |
| Revision date | - |
| Supersedes date | - |

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

| | |
|----------------------|---|
| Identified uses | Blood collection (In-Vitro Diagnostic) device |
| Uses advised against | None known. |

1.3. Details of the supplier of the safety data sheet

Supplier

| | |
|----------------|---|
| Company name | Becton, Dickinson and Company |
| Address | Belliver Industrial Estate Belliver Way, Roborough, Plymouth , PL6 7BP, United Kingdom |
| Telephone | +44 (0) 1752 701281 |
| Contact person | Not available. |
| e-mail | pas_tech_services@bd.com |

| | |
|---------------------------------|--|
| 1.4. Emergency telephone number | Chemtrec EU 703-527-3887 US 1-800-424-9300 |
|---------------------------------|--|

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

| | |
|----------------|---|
| Hazard summary | Not regarded as a health or environmental hazard under current legislation. Low hazard for recommended handling by trained personnel. |
|----------------|---|

2.2. Label elements

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

| | |
|-------------------|--|
| Hazard pictograms | None. |
| Signal word | None. |
| Hazard statements | The mixture does not meet the criteria for classification. |

Precautionary statements

| | |
|------------|--|
| Prevention | Observe good industrial hygiene practices. |
| Response | Wash hands after handling. |
| Storage | Store away from incompatible materials. |
| Disposal | Dispose of waste and residues in accordance with local authority requirements. |

| | |
|--------------------------------|-------|
| Supplemental label information | None. |
|--------------------------------|-------|

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|--------------------|---|
| 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 |
|------------------------|-------------------|----------------------|------------------------|-----------|-------|
| Theophylline | < 1 | 58-55-9 200-385-7 | - | - | |
| Classification: | Acute Tox. 3;H301 | | | | |

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. Components not listed are either non-hazardous or are below reportable limits.

SECTION 4: First aid measures

General information No specific first aid measures noted.

4.1. Description of first aid measures

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact Wash skin with soap and water. Get medical attention if irritation persists after washing.
Eye contact Flush eyes with water as a precaution. If irritation occurs, get medical assistance.
Ingestion Rinse mouth. Get medical attention if any discomfort occurs.

4.2. Most important symptoms and effects, both acute and delayed Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

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

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture By heating and fire, harmful vapours/gases may be formed.

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.
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 Avoid contact with eyes and prolonged skin contact.
For emergency responders Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions Environmental manager must be informed of all major spillages.

6.3. Methods and material for containment and cleaning up Wipe up spilled material and place in a suitable container for disposal. Following product recovery, flush area with water.

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 Avoid contact with eyes and prolonged skin contact. Observe good laboratory hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities Store in a cool, dry, well-ventilated place. Keep container closed. Store away from incompatible materials.

7.3. Specific end use(s) Blood collection (In-Vitro Diagnostic) device.

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. |
| Exposure guidelines | No exposure limits noted for ingredient(s). |
| 8.2. Exposure controls | |
| Appropriate engineering controls | No particular 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 | Risk of contact: Wear approved safety goggles. |
| Skin protection | |
| - Hand protection | For prolonged or repeated skin contact use suitable protective gloves. Nitrile gloves are recommended. Suitable gloves can be recommended by the glove supplier. |
| - Other | No protection is ordinarily required under normal conditions of use. |
| Respiratory protection | Under normal conditions, respirator is not normally required. |
| Thermal hazards | None. |
| Hygiene measures | Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. |
| Environmental exposure controls | Environmental manager must be informed of all major spillages. |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

| | |
|--|-----------------|
| Physical state | Liquid. |
| Form | Liquid. |
| Colour | Yellow. |
| Odour | Odourless. |
| Odour threshold | Not applicable. |
| pH | Not available. |
| Melting point/freezing point | Not available. |
| Initial boiling point and boiling range | Not available. |
| Flash point | Not applicable. |
| Evaporation rate | Not available. |
| Flammability (solid, gas) | Not applicable. |

Upper/lower flammability or explosive limits

| | |
|--|------------------------------|
| Flammability limit - lower (%) | Not applicable. |
| Flammability limit - upper (%) | Not applicable. |
| Vapour pressure | Not available. |
| Vapour density | Not available. |
| Relative density | Not available. |
| Solubility(ies) | Completely soluble in water. |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not applicable. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Explosive properties | Not explosive. |

| | |
|-------------------------------|---|
| Oxidizing properties | Not oxidising. |
| 9.2. Other information | No relevant additional information available. |

SECTION 10: Stability and reactivity

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|---|---|
| 10.1. Reactivity | The product is stable and non reactive under normal conditions of use, storage and transport. |
| 10.2. Chemical stability | Stable at normal conditions. |
| 10.3. Possibility of hazardous reactions | Will not occur. |
| 10.4. Conditions to avoid | Contact with incompatible materials. |
| 10.5. Incompatible materials | Strong oxidising agents. |
| 10.6. Hazardous decomposition products | None expected under normal conditions of use. |

SECTION 11: Toxicological information

| | |
|---|---|
| General information | Under normal conditions of intended use, this material does not pose a risk to health. |
| Information on likely routes of exposure | |
| Inhalation | Under normal conditions of intended use, this material is not expected to be an inhalation hazard. |
| Skin contact | Prolonged contact may cause dryness of the skin. |
| Eye contact | Direct contact with eyes may cause temporary irritation. |
| Ingestion | Ingestion may cause irritation and malaise. |
| Symptoms | Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. |

11.1. Information on toxicological effects

| | | |
|--|---|--------------|
| Acute toxicity | Not expected to be acutely toxic. | |
| Components | Species | Test results |
| Theophylline (CAS 58-55-9) | | |
| Acute | | |
| Oral | | |
| LD50 | Rat | 272 mg/kg |
| Skin corrosion/irritation | Based on available data, the classification criteria are not met. | |
| Serious eye damage/eye irritation | Based on available data, the classification criteria are not met. | |
| Respiratory sensitisation | Based on available data, the classification criteria are not met. | |
| Skin sensitisation | Based on available data, the classification criteria are not met. | |
| Germ cell mutagenicity | Based on available data, the classification criteria are not met. | |
| Carcinogenicity | Based on available data, the classification criteria are not met. | |
| IARC Monographs. Overall Evaluation of Carcinogenicity | | |
| Theophylline (CAS 58-55-9) | 3 Not classifiable as to carcinogenicity to humans. | |
| Reproductive toxicity | Based on available data, the classification criteria are not met. | |
| Specific target organ toxicity - single exposure | Based on available data, the classification criteria are not met. | |
| Specific target organ toxicity - repeated exposure | Based on available data, the classification criteria are not met. | |
| Aspiration hazard | Based on available data, the classification criteria are not met. | |
| Mixture versus substance information | None known. | |
| Other information | No additional adverse health effects noted. | |

SECTION 12: Ecological information

| | |
|--|--|
| 12.1. Toxicity | The product components are 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 available. |
| 12.3. Bioaccumulative potential | |

**Partition coefficient
n-octanol/water (log Kow)**

Theophylline (CAS 58-55-9)

-0.02

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil This product is water soluble and may disperse in soil.

Mobility in general No data available.

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

12.6. Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

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

EU waste code 16 03 04
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. Do not discharge into drains, water courses or onto the ground.

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

This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. The product does not need to be labelled in accordance with EC directives or respective national laws.

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

DNEL: Derived No-Effect Level.
PNEC: Predicted No-Effect Concentration.
PBT: Persistent, bioaccumulative and toxic.
LD50: Lethal Dose, 50%.

References

ACGIH: American Conference of Governmental and Industrial Hygienists.
US. IARC Monographs on Occupational Exposures to Chemical Agents
National Toxicology Program (NTP) Report on Carcinogens

Information on evaluation method leading to the classification of mixture

The mixture is classified based on test data for physical hazards. The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available. For details, refer to Sections 9, 11 and 12.

Full text of any H-statements not written out in full under Sections 2 to 15

H301 Toxic if swallowed.

Training information

Follow training instructions when handling this material.

Disclaimer

To the best of our knowledge, the information contained herein is accurate. However, neither BD nor any of its subsidiaries assumes any liability whatsoever for 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.