

Part Number: **BITP1673** Version No: **1.1** Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878) Chemwatch Hazard Alert Code: 2 Issue Date: 30/05/2023

Print Date: 30/05/2023 S.REACH.GB-NIR.EN

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

# 1.1. Product Identifier

| Product name   | Recombinant Human Cardiac Troponin I-T-C Complex |  |  |  |
|--|--|--|--|--|
| Synonyms   | Not Available                                    |  |  |  |
| Other means of identification  | Not Available                                    |  |  |  |
| 1.2. Relevant identified uses of the substance or mixture and uses advised against |  |  |  |  |

| Relevant identified uses | Use according to manufacturer's directions. |
|--------------------------|---|

| Uses advised against | No specific uses advised against are identified. |
|----------------------|--|

# 1.3. Details of the manufacturer or supplier of the safety data sheet

| Registered company name | Apollo Scientific                               |  |  |  |
|-------------------------|---|--|--|--|
| Address                 | Whitefield Road, Bredbury SK62QR United Kingdom |  |  |  |
| Telephone               | 01614060505                                     |  |  |  |
| Fax                     | 0161 406 0506                                   |  |  |  |
| Website                 | http://www.apolloscientific.co.uk/              |  |  |  |
| Email                   | sales@apolloscientific.co.uk                    |  |  |  |

## 1.4. Emergency telephone number

| Association / Organisation        | Not Available |
|-----------------------------------|---------------|
| Emergency telephone<br>numbers    | Not Available |
| Other emergency telephone numbers | Not Available |

# **SECTION 2 Hazards identification**

## 2.1. Classification of the substance or mixture

| Classification according to<br>regulation (EC) No 1272/2008<br>[CLP] and amendments <sup>[1]</sup> | H335 - Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, H315 - Skin Corrosion/Irritation Category 2,<br>H319 - Serious Eye Damage/Eye Irritation Category 2 |
|--|--|
| Legend:  | 1. Classified by Chernwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI  |

## 2.2. Label elements

| Hazard pictogram(s) |                                   |  |  |
|---------------------|-----------------------------------|--|--|
| Signal word         | Warning                           |  |  |
| Hazard statement(s) |                                   |  |  |
| H335                | May cause respiratory irritation. |  |  |
| H315                | Causes skin irritation.           |  |  |

H319 Causes serious eye irritation.

## **Supplementary Phrases**

Not Applicable

# Precautionary statement(s) Prevention

| P271 | Use only outdoors or in a well-ventilated area.                                  |
|------|--|
| P261 | Avoid breathing dust/fumes.  |
| P280 | Wear protective gloves, protective clothing, eye protection and face protection. |
| P264 | Wash all exposed external body areas thoroughly after handling.                  |

# Precautionary statement(s) Response

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

## Precautionary statement(s) Storage

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

# Precautionary statement(s) Disposal

P501 [

Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

## 2.3. Other hazards

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

# **SECTION 3 Composition / information on ingredients**

## 3.1.Substances

See 'Composition on ingredients' in Section 3.2

## 3.2.Mixtures

| 1. CAS No<br>2.EC No<br>3.Index No<br>4.REACH No | %[weight]   | Name  | Classification according to regulation (EC)<br>No 1272/2008 [CLP] and amendments | SCL /<br>M-Factor | Nanoform Particle<br>Characteristics |
|--|---|---|--|-------------------|--------------------------------------|
| Not Available                                    | 100   | Recombinant Human Cardiac<br>Troponin I-T-C Complex | Not Applicable   | Not<br>Applicable | Not Available                        |
| Legend:  | <ol> <li>Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&amp;L * EU<br/>IOELVs available; [e] Substance identified as having endocrine disrupting properties</li> </ol> |   |  |                   |                                      |

## **SECTION 4 First aid measures**

## 4.1. Description of first aid measures

| Eye Contact  | <ul> <li>If this product comes in contact with the eyes:</li> <li>Wash out immediately with fresh running water.</li> <li>Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.</li> <li>Seek medical attention without delay; if pain persists or recurs seek medical attention.</li> <li>Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>                                  |
|--------------|--|
| Skin Contact | <ul> <li>If skin contact occurs:</li> <li>Immediately remove all contaminated clothing, including footwear.</li> <li>Flush skin and hair with running water (and soap if available).</li> <li>Seek medical attention in event of irritation.</li> </ul>  |
| Inhalation   | <ul> <li>If fumes or combustion products are inhaled remove from contaminated area.</li> <li>Lay patient down. Keep warm and rested.</li> <li>Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.</li> <li>Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.</li> <li>Transport to hospital, or doctor, without delay.</li> </ul> |
| Ingestion    | <ul> <li>Immediately give a glass of water.</li> <li>First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.</li> </ul>  |

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

See Section 11

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

Treat symptomatically.

# **SECTION 5 Firefighting measures**

## 5.1. Extinguishing media

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

## 5.2. Special hazards arising from the substrate or mixture

| Fire Incompatibility         | None known.  |  |  |
|------------------------------|--|--|--|
| 5.3. Advice for firefighters |  |  |  |
|                              | <ul> <li>Alert Fire Brigade and tell them location and nature of hazard.</li> <li>Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>Prevent, by any means available, spillage from entering drains or water courses.</li> </ul> |  |  |

| Fire Fighting         | <ul> <li>Use fire fighting procedures suitable for surrounding area.</li> <li>DO NOT approach containers suspected to be hot.</li> <li>Cool fire exposed containers with water spray from a protected location.</li> <li>If safe to do so, remove containers from path of fire.</li> <li>Equipment should be thoroughly decontaminated after use.</li> </ul> |
|-----------------------|--|
| Fire/Explosion Hazard | <ul> <li>Non combustible.</li> <li>Not considered a significant fire risk, however containers may burn.</li> <li>May emit poisonous fumes.</li> <li>May emit corrosive fumes.</li> </ul>   |

# **SECTION 6** Accidental release measures

# 6.1. Personal precautions, protective equipment and emergency procedures

See section 8

## 6.2. Environmental precautions

See section 12

## 6.3. Methods and material for containment and cleaning up

| Minor Spills | <ul> <li>Clean up all spills immediately.</li> <li>Avoid breathing dust and contact with skin and eyes.</li> <li>Wear protective clothing, gloves, safety glasses and dust respirator.</li> <li>Use dry clean up procedures and avoid generating dust.</li> <li>Sweep up, shovel up or</li> <li>Vacuum up (consider explosion-proof machines designed to be grounded during storage and use).</li> <li>Place spilled material in clean, dry, sealable, labelled container.</li> </ul>   |
|--------------|---|
| Major Spills | <ul> <li>Moderate hazard.</li> <li>CAUTION: Advise personnel in area.</li> <li>Alert Emergency Services and tell them location and nature of hazard.</li> <li>Control personal contact by wearing protective clothing.</li> <li>Prevent, by any means available, spillage from entering drains or water courses.</li> <li>Recover product wherever possible.</li> <li>IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.</li> <li>ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.</li> <li>If contamination of drains or waterways occurs, advise Emergency Services.</li> </ul> |

## 6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

# **SECTION 7 Handling and storage**

| 7.1. Precautions for safe hand | ling   |
|--------------------------------|--|
| Safe handling                  | <ul> <li>Avoid all personal contact, including inhalation.</li> <li>Wear protective clothing when risk of exposure occurs.</li> <li>Use in a well-ventilated area.</li> <li>Prevent concentration in hollows and sumps.</li> <li>DO NOT enter confined spaces until atmosphere has been checked.</li> <li>DO NOT allow material to contact humans, exposed food or food utensils.</li> <li>Avoid contact with incompatible materials.</li> <li>When handling, DO NOT eat, drink or smoke.</li> </ul> |

|                               | <ul> <li>Keep containers securely sealed when not in use.</li> <li>Avoid physical damage to containers.</li> <li>Always wash hands with soap and water after handling.</li> <li>Work clothes should be laundered separately. Launder contaminated clothing before re-use.</li> <li>Use good occupational work practice.</li> <li>Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul>  |
|-------------------------------|--|
| Fire and explosion protection | See section 5  |
| Other information             | <ul> <li>Store in original containers.</li> <li>Keep containers securely sealed.</li> <li>Store in a cool, dry area protected from environmental extremes.</li> <li>Store away from incompatible materials and foodstuff containers.</li> <li>Protect containers against physical damage and check regularly for leaks.</li> <li>Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>For major quantities: <ul> <li>Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams).</li> <li>Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.</li> </ul> </li> </ul> |

# 7.2. Conditions for safe storage, including any incompatibilities

| Suitable container   | <ul> <li>Polyethylene or polypropylene container.</li> <li>Check all containers are clearly labelled and free from leaks.</li> </ul> |
|--|--|
| Storage incompatibility  | ► Store at-20°c  |
| Hazard categories in<br>accordance with Regulation<br>(EC) No 1272/2008  | Not Available  |
| Qualifying quantity (tonnes) of<br>dangerous substances as<br>referred to in Article 3(10) for<br>the application of | Not Available  |

# 7.3. Specific end use(s)

See section 1.2

# **SECTION 8 Exposure controls / personal protection**

# 8.1. Control parameters

| Ingredient    | DNELs<br>Exposure Pattern Worker | PNECs<br>Compartment |  |
|---------------|----------------------------------|----------------------|--|
| Not Available | Not Available                    | Not Available        |  |

\* Values for General Population

# Occupational Exposure Limits (OEL)

| INGREDIENT DATA |               |               |               |               |               |               |
|-----------------|---------------|---------------|---------------|---------------|---------------|---------------|
| Source          | Ingredient    | Material name | TWA           | STEL          | Peak          | Notes         |
| Not Available   | Not Available | Not Available | Not Available | Not Available | Not Available | Not Available |

Not Applicable

# Emergency Limits

| Ingredient  | TEEL-1        | TEEL-2        |               | TEEL-3        |
|---|---------------|---------------|---------------|---------------|
| Recombinant Human Cardiac<br>Troponin I-T-C Complex | Not Available | Not Available |               | Not Available |
| Ingredient  | Original IDLH |               | Revised IDLH  |               |
| Recombinant Human Cardiac<br>Troponin I-T-C Complex | Not Available |               | Not Available |               |

# 8.2. Exposure controls

| 8.2.1. Appropriate engineering controls | Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can<br>be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.<br>The basic types of engineering controls are:<br>Process controls which involve changing the way a job activity or process is done to reduce the risk.<br>Enclosure and/or isolation of emission source which keeps a selected hazard 'physically' away from the worker and ventilation that strategically<br>'adds' and 'removes' air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a<br>ventilation system must match the particular process and chemical or contaminant in use.<br>Employers may need to use multiple types of controls to prevent employee overexposure.<br><ul> <li>Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain<br/>proportion will be powdered by mutual friction.</li> <li>If in spite of local exhaust an adverse concentration of the substance in air could occur, respiratory protection should be considered.</li> </ul> |
|---|---|
|---|---|

|  | Such protection might consist of:<br>(a): particle dust respirators, if necessary, combined with an absorption cartridge;<br>(b): filter respirators with absorption cartridge or canister of the right type;<br>(c): fresh-air hoods or masks.<br>Air contaminants generated in the workplace possess varying 'escape' velocities which, in turn, determine the 'capture velocities' of fresh<br>circulating air required to effectively remove the contaminant.   |   |   |  |  |  |  |
|--|---|---|---|--|--|--|--|
|  | Type of Contaminant:  | Air Speed:  |   |  |  |  |  |
|  | direct spray, spray painting in shallow booths, drum filling, generation into zone of rapid air motion)   | 1-2.5 m/s (200-500<br>f/min.)   |   |  |  |  |  |
|  | grinding, abrasive blasting, tumbling, high speed wheel ge very high rapid air motion).   | 2.5-10 m/s (500-2000<br>f/min.)   |   |  |  |  |  |
|  | Within each range the appropriate value depends on:   |   |   |  |  |  |  |
|  | Lower end of the range  | Upper end of the range  |   |  |  |  |  |
|  | 1: Room air currents minimal or favourable to capture   | 1: Disturbing room air currents   |   |  |  |  |  |
|  | 2: Contaminants of low toxicity or of nuisance value only.  | 2: Contaminants of high toxicity  |   |  |  |  |  |
|  | 3: Intermittent, low production.  | 3: High production, heavy use   |   |  |  |  |  |
|  | 4: Large hood or large air mass in motion   | 4: Small hood-local control only  |   |  |  |  |  |
|  | Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally det with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a m 4-10 m/s (800-2000 f/min) for extraction of crusher dusts generated 2 metres distant from the extraction point. Other mechanical consid producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors or more when extraction systems are installed or used.   |   |   |  |  |  |  |
| 8.2.2. Individual protection<br>measures, such as personal<br>protective equipment |   |   |   |  |  |  |  |
| Eye and face protection  | <ul> <li>Safety glasses with side shields.</li> <li>Chemical goggles.</li> <li>Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]</li> </ul>   |   |   |  |  |  |  |
| Skin protection  | See Hand protection below   |   |   |  |  |  |  |
| Hands/feet protection  | The selection of suitable gloves does not only depend on the manufacturer. Where the chemical is a preparation of sever and has therefore to be checked prior to the application. The exact break through time for substances has to be obtimaking a final choice. Personal hygiene is a key element of effective hand care. Or washed and dried thoroughly. Application of a non-perfume Suitability and durability of glove type is dependent on usage frequency and duration of contact, chemical resistance of glove material, glove thickness and detertity Select gloves tested to a relevant standard (e.g. Europe EN When prolonged or frequently repeated contact may occur minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recomment. Some glove polymer types are less affected by movement. Contaminated gloves should be replaced. As defined in ASTM F-739-96 in any application, gloves are Excellent when breakthrough time < 20 min the second provide time should be emphasised that glove thickness is not necess efficiency of the glove will be dependent on the exact compromised applications, gloves with a thickness typically glit should be emphasised that glove thickness is not necess efficiency of the glove will be dependent on the exact compromised ration of the task requirements and knowledge of b Glove thickness may also vary depending on the glove material dates should always be taken into account to ensure selection. Note: Depending on the activity being conducted, gloves of -Thinner gloves (down to 0.1 mm or less) may be required likely to give short duration protection and would normally the -Thicker gloves (up to 3 mm or more) may be required who puncture potential Glove so or chean hands. After using glove moisturiser is recommended. | ral substances, the resistance of the<br>ained from the manufacturer of the<br>Gloves must only be worn on clean<br>ad moisturiser is recommended.<br>ge. Important factors in the selection<br>of the selection class of<br>al equivalent) is recommended.<br>tion class of 3 or higher (breakthro-<br>noted.<br>t and this should be taken into acco-<br>e rated as:<br>greater than 0.35 mm, are recomm-<br>tarily a good predictor of glove resi-<br>position of the glove material. There<br>reakthrough times.<br>nufacturer, the glove type and the<br>on of the most appropriate glove for<br>varying thickness may be require-<br>where a high degree of manual de<br>pois just for single use applications, the<br>ere there is a mechanical (as well a | e glove material can not l<br>protective gloves and har<br>hands. After using gloves<br>on of gloves include:<br>r national equivalent).<br>f 5 or higher (breakthroug<br>bugh time greater than 60<br>count when considering glov<br>stance to a specific chemi<br>efore, glove selection sho<br>glove model. Therefore, th<br>or the task.<br>d for specific tasks. For ex<br>exterity is needed. However<br>then disposed of.<br>as a chemical) risk i.e. wh | be calculated in advance<br>s to be observed when<br>s, hands should be<br>h time greater than 240<br>minutes according to EN<br>oves for long-term use.<br>cal, as the permeation<br>uld also be based on<br>he manufacturers technical<br>cample:<br>er, these gloves are only<br>ere there is abrasion or |  |  |  |

|                  | Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present. |
|------------------|--|
| Body protection  | See Other protection below   |
| Other protection | <ul> <li>Overalls.</li> <li>P.V.C apron.</li> <li>Barrier cream.</li> <li>Skin cleansing cream.</li> <li>Eye wash unit.</li> </ul>   |

## **Respiratory protection**

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

| Required Minimum Protection Factor | Half-Face Respirator | Full-Face Respirator | Powered Air Respirator |
|------------------------------------|----------------------|----------------------|------------------------|
| up to 10 x ES                      | P1<br>Air-line*      | -                    | PAPR-P1<br>-           |
| up to 50 x ES                      | Air-line**           | P2                   | PAPR-P2                |
| up to 100 x ES                     | -                    | P3                   | -                      |
|                                    |                      | Air-line*            | -                      |
| 100+ x ES                          | -                    | Air-line**           | PAPR-P3                |

\* - Negative pressure demand \*\* - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

· Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.

• The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).

Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.

Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
 Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)

· Use approved positive flow mask if significant quantities of dust becomes airborne.

· Try to avoid creating dust conditions.

## 8.2.3. Environmental exposure controls

See section 12

# **SECTION 9** Physical and chemical properties

## 9.1. Information on basic physical and chemical properties

| Appearance                                   | Not Available |   |                |
|--|---------------|---|----------------|
| Physical state                               | Solid         | Relative density (Water = 1)            | Not Available  |
| Odour  | Not Available | Partition coefficient n-octanol / water | Not Available  |
| Odour threshold                              | Not Available | Auto-ignition temperature (°C)          | Not Available  |
| pH (as supplied)                             | Not Available | Decomposition<br>temperature (°C)       | Not Available  |
| Melting point / freezing point<br>(°C)       | Not Available | Viscosity (cSt)                         | Not Available  |
| Initial boiling point and boiling range (°C) | Not Available | Molecular weight (g/mol)                | Not Available  |
| Flash point (°C)                             | Not Available | Taste                                   | Not Available  |
| Evaporation rate                             | Not Available | Explosive properties                    | Not Available  |
| Flammability                                 | Not Available | Oxidising properties                    | Not Available  |
| Upper Explosive Limit (%)                    | Not Available | Surface Tension (dyn/cm or<br>mN/m)     | Not Applicable |
| Lower Explosive Limit (%)                    | Not Available | Volatile Component (%vol)               | Not Available  |
| Vapour pressure (kPa)                        | Not Available | Gas group                               | Not Available  |

| Solubility in water      | Not Available | pH as a solution (1%)                | Not Available |
|--------------------------|---------------|--------------------------------------|---------------|
| Vapour density (Air = 1) | Not Available | VOC g/L                              | Not Available |
| Nanoform Solubility      | Not Available | Nanoform Particle<br>Characteristics | Not Available |
| Particle Size            | Not Available |                                      |               |

# 9.2. Other information

Not Available

# **SECTION 10 Stability and reactivity**

| 10.1.Reactivity                           | See section 7.2  |  |
|---|--|--|
| 10.2. Chemical stability                  | <ul> <li>Unstable in the presence of incompatible materials.</li> <li>Product is considered stable.</li> <li>Hazardous polymerisation will not occur.</li> </ul> |  |
| 10.3. Possibility of hazardous reactions  | section 7.2  |  |
| 10.4. Conditions to avoid                 | See section 7.2  |  |
| 10.5. Incompatible materials              | See section 7.2  |  |
| 10.6. Hazardous<br>decomposition products | See section 5.3  |  |

# **SECTION 11 Toxicological information**

# 11.1. Information on toxicological effects

| 0   |   |  |  |
|---|---|--|--|
| Inhaled   | The material can cause respiratory irritation in some perso<br>Persons with impaired respiratory function, airway disease<br>if excessive concentrations of particulate are inhaled.<br>If prior damage to the circulatory or nervous systems has o<br>conducted on individuals who may be exposed to further ri  | s and conditions such as emphys  | sema or chronic bronchitis, may incur further disability<br>been sustained, proper screenings should be  |
| Ingestion   | The material has <b>NOT</b> been classified by EC Directives or other classification systems as 'harmful by ingestion'. This is because of the lack of corroborating animal or human evidence.  |  |  |
| Skin Contact  | This material can cause inflammation of the skin on contact in some persons.<br>The material may accentuate any pre-existing dermatitis condition<br>Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage<br>following entry through wounds, lesions or abrasions.<br>Open cuts, abraded or irritated skin should not be exposed to this material<br>Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin<br>prior to the use of the material and ensure that any external damage is suitably protected. |  |  |
| Еуе   | This material can cause eye irritation and damage in some persons.  |  |  |
| Chronic   | Long-term exposure to respiratory irritants may result in airways disease, involving difficulty breathing and related whole-body problems.<br>Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.  |  |  |
|   |   |  |  |
| Recombinant Human Cardiac                           | тохісіту  | IRRITATION   |  |
| Troponin I-T-C Complex                              | Not Available   | Not Available  |  |
| Legend:   | <ol> <li>Value obtained from Europe ECHA Registered Substant<br/>specified data extracted from RTECS - Register of Toxic E</li> </ol>   | •  | ined from manufacturer's SDS. Unless otherwise   |
| Recombinant Human Cardiac<br>Troponin I-T-C Complex | Asthma-like symptoms may continue for months or even ye<br>known as reactive airways dysfunction syndrome (RADS)<br>criteria for diagnosing RADS include the absence of previo<br>asthma-like symptoms within minutes to hours of a docum<br>airflow pattern on lung function tests, moderate to severe b<br>lymphocytic inflammation, without eosinophilia. RADS (or<br>a the concentration of and duration of exposure to the irritatin<br>result of exposure due to high concentrations of irritating su<br>disorder is characterized by difficulty breathing, cough and   | which can occur after exposure to<br>bus airways disease in a non-atop<br>ented exposure to the irritant. Ot<br>oronchial hyperreactivity on meth<br>asthma) following an irritating inh<br>ng substance. On the other hand<br>ubstance (often particles) and is | o high levels of highly irritating compound. Main<br>bic individual, with sudden onset of persistent<br>her criteria for diagnosis of RADS include a reversible<br>acholine challenge testing, and the lack of minimal<br>alation is an infrequent disorder with rates related to<br>hindustrial bronchitis is a disorder that occurs as a |
| Acute Toxicity                                      | ×   | Carcinogenicity  | ×  |
| Skin Irritation/Corrosion                           | ¥   | Reproductivity   | ×  |
| Serious Eye Damage/Irritation                       | ¥   | STOT - Single Exposure   | ✓  |
| Respiratory or Skin<br>sensitisation                | ×   | STOT - Repeated Exposure   | ×  |

Mutagenicity 🗙

Aspiration Hazard

x

Legend: X – Data

Data either not available or does not fill the criteria for classification
 Data available to make classification

## 11.2 Information on other hazards

## 11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

## 11.2.2. Other information

See Section 11.1

# **SECTION 12 Ecological information**

## 12.1. Toxicity

| Recombinant Human Cardiac | Endpoint   | Test Duration (hr) | Species       | Value         | Source        |
|---------------------------|--|--------------------|---------------|---------------|---------------|
| Troponin I-T-C Complex    | Not Available  | Not Available      | Not Available | Not Available | Not Available |
| Legend:                   | Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA,                                       |                    |               |               |               |
|                           | Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan - Bioconcentration Data 8. Vendor Data |                    |               |               |               |

#### DO NOT discharge into sewer or waterways.

## 12.2. Persistence and degradability

|                             |            | Persistence: Air                      |
|-----------------------------|------------|---------------------------------------|
| No Data available for all i | ngredients | No Data available for all ingredients |

| 12.3. | Bioaccumu | lative | potential |
|-------|-----------|--------|-----------|
|-------|-----------|--------|-----------|

| Ingredient | Bioaccumulation                       |  |
|------------|---------------------------------------|--|
|            | No Data available for all ingredients |  |
|            |                                       |  |

## 12.4. Mobility in soil

| Ingredient | Mobility                              |
|------------|---------------------------------------|
|            | No Data available for all ingredients |

## 12.5. Results of PBT and vPvB assessment

|                         | Р                          | В             | Т             |  |  |
|-------------------------|----------------------------|---------------|---------------|--|--|
| Relevant available data | Not Available              | Not Available | Not Available |  |  |
| PBT                     | ×                          | ×             | ×             |  |  |
| vPvB                    | ×                          | X             | ×             |  |  |
| PBT Criteria fulfilled? | PBT Criteria fulfilled? No |               |               |  |  |
| vPvB                    | No                         |               |               |  |  |

## 12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

#### 12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.

# **SECTION 13 Disposal considerations**

# 13.1. Waste treatment methods • Recycle wherever possible or consult manufacturer for recycling options.

| Product / Packaging disposal | <ul> <li>Consult State Land Waste Management Authority for disposal.</li> <li>Bury residue in an authorised landfill.</li> <li>Recycle containers if possible, or dispose of in an authorised landfill.</li> </ul> |
|------------------------------|--|
| Waste treatment options      | Not Available  |
| Sewage disposal options      | Not Available  |

# **SECTION 14 Transport information**

# Labels Required

| Marine Pollutant | NO             |
|------------------|----------------|
| HAZCHEM          | Not Applicable |

# Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| 14.1. UN number or ID number  | Not Applicable                 |                |  |
|-------------------------------|--------------------------------|----------------|--|
| 14.2. UN proper shipping name | Not Applicable                 |                |  |
| 14.3. Transport hazard        | Class Not Applica              | ble            |  |
| class(es)                     | Subsidiary risk Not Applica    | ble            |  |
| 14.4. Packing group           | Not Applicable                 |                |  |
| 14.5. Environmental hazard    | Not Applicable                 |                |  |
|                               | Hazard identification (Kemler) | Not Applicable |  |
|                               | Classification code            | Not Applicable |  |
| 14.6. Special precautions for | Hazard Label                   | Not Applicable |  |
| user                          | Special provisions             | Not Applicable |  |
|                               | Limited quantity               | Not Applicable |  |
|                               | Tunnel Restriction Code        | Not Applicable |  |

# Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| Not Applicable  |  |  |   |
|---|--|--|---|
| Not Applicable  |  |  |   |
| ICAO/IATA Class   | Not Applicable   |  |   |
| ICAO / IATA Subrisk                                       | Not Applicable   |  |   |
| ERG Code  | ERG Code Not Applicable  |  |   |
| Not Applicable  |  |  |   |
| Not Applicable  |  |  |   |
| Special provisions  |  | Not Applicable   |   |
| Cargo Only Packing Instructions                           |  | Not Applicable   |   |
| Cargo Only Maximum Qty / Pack                             |  | Not Applicable   |   |
| Passenger and Cargo Packing Instructions                  |  | Not Applicable   |   |
| Passenger and Cargo Maximum Qty / Pack                    |  | Not Applicable   |   |
| Passenger and Cargo Limited Quantity Packing Instructions |  | Not Applicable   |   |
| Passenger and Cargo                                       | Limited Maximum Qty / Pack   | Not Applicable   |   |
|   | Not Applicable         ICAO/IATA Class         ICAO / IATA Subrisk         ERG Code         Not Applicable         Special provisions         Cargo Only Packing Ir         Cargo Only Maximum         Passenger and Cargo         Passenger and Cargo         Passenger and Cargo | Not Applicable         ICAO/IATA Class       Not Applicable         ICAO / IATA Subrisk       Not Applicable         ERG Code       Not Applicable         Not Applicable       Not Applicable         Not Applicable       Special provisions         Cargo Only Packing Instructions       Cargo Only Maximum Qty / Pack         Passenger and Cargo Maximum Qty / Pack       Passenger and Cargo Maximum Qty / Pack | Not Applicable         ICAO/IATA Class       Not Applicable         ICAO / IATA Subrisk       Not Applicable         ERG Code       Not Applicable         Not Applicable       Not Applicable         Not Applicable       Special provisions         Special provisions       Not Applicable         Cargo Only Packing Instructions       Not Applicable         Cargo Only Maximum Qty / Pack       Not Applicable         Passenger and Cargo Packing Instructions       Not Applicable         Passenger and Cargo Maximum Qty / Pack       Not Applicable         Passenger and Cargo Limited Quantity Packing Instructions       Not Applicable |

# Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| 14.1. UN number                    | Not Applicable   |  |  |
|------------------------------------|--|--|--|
| 14.2. UN proper shipping name      | Not Applicable   |  |  |
| 14.3. Transport hazard class(es)   | IMDG Class     Not Applicable       IMDG Subrisk     Not Applicable                      |  |  |
| 14.4. Packing group Not Applicable |  |  |  |
| 14.5. Environmental hazard         | Not Applicable   |  |  |
| 14.6. Special precautions for user | EMS NumberNot ApplicableSpecial provisionsNot ApplicableLimited QuantitiesNot Applicable |  |  |

# Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| 14.1. UN number                    | Not Applicable  |  |  |
|------------------------------------|---|--|--|
| 14.2. UN proper shipping name      | Not Applicable  |  |  |
| 14.3. Transport hazard class(es)   | Not Applicable Not Applicable   |  |  |
| 14.4. Packing group                | Not Applicable  |  |  |
| 14.5. Environmental hazard         | Not Applicable  |  |  |
| 14.6. Special precautions for user | Classification codeNot ApplicableSpecial provisionsNot ApplicableLimited quantityNot Applicable |  |  |

| Equipment required | Not Applicable |
|--------------------|----------------|
| Fire cones number  | Not Applicable |

## 14.7. Maritime transport in bulk according to IMO instruments

## 14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

#### 14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

| Product name | Group |
|--------------|-------|
|              |       |

## 14.7.3. Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|--------------|-----------|
|              |           |

## **SECTION 15 Regulatory information**

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

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

# Information according to 2012/18/EU (Seveso III):

Seveso Category Not Available

#### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

# ECHA SUMMARY

Not Applicable

## **National Inventory Status**

| National Inventory                                 | Status  |
|--|---|
| Australia - AIIC / Australia<br>Non-Industrial Use | Not Available   |
| Canada - DSL                                       | Not Available   |
| Canada - NDSL                                      | Not Available   |
| China - IECSC                                      | Not Available   |
| Europe - EINEC / ELINCS / NLP                      | Not Available   |
| Japan - ENCS                                       | Not Available   |
| Korea - KECI                                       | Not Available   |
| New Zealand - NZIoC                                | Not Available   |
| Philippines - PICCS                                | Not Available   |
| USA - TSCA   | Not Available   |
| Taiwan - TCSI                                      | Not Available   |
| Mexico - INSQ                                      | Not Available   |
| Vietnam - NCI                                      | Not Available   |
| Russia - FBEPH                                     | Not Available   |
| Legend:  | Yes = All CAS declared ingredients are on the inventory<br>No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration. |

# **SECTION 16 Other information**

| Revision Date | 30/05/2023 |
|---------------|------------|
| Initial Date  | 30/05/2023 |

## Full text Risk and Hazard codes

#### Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered. For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

## Definitions and abbreviations

PC-TWA: Permissible Concentration-Time Weighted Average

PC-STEL: Permissible Concentration-Short Term Exposure Limit

# Issue Date: 30/05/2023 Print Date: 30/05/2023

# **Recombinant Human Cardiac Troponin I-T-C Complex**

IARC: International Agency for Research on Cancer ACGIH: American Conference of Governmental Industrial Hygienists STEL: Short Term Exposure Limit TEEL: Temporary Emergency Exposure Limit。 IDLH: Immediately Dangerous to Life or Health Concentrations ES: Exposure Standard OSF: Odour Safety Factor NOAEL :No Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level TLV: Threshold Limit Value LOD: Limit Of Detection OTV: Odour Threshold Value BCF: BioConcentration Factors BEI: Biological Exposure Index AIIC: Australian Inventory of Industrial Chemicals DSL: Domestic Substances List NDSL: Non-Domestic Substances List IECSC: Inventory of Existing Chemical Substance in China EINECS: European INventory of Existing Commercial chemical Substances ELINCS: European List of Notified Chemical Substances NLP: No-Longer Polymers ENCS: Existing and New Chemical Substances Inventory KECI: Korea Existing Chemicals Inventory NZIoC: New Zealand Inventory of Chemicals PICCS: Philippine Inventory of Chemicals and Chemical Substances TSCA: Toxic Substances Control Act TCSI: Taiwan Chemical Substance Inventory INSQ: Inventario Nacional de Sustancias Químicas NCI: National Chemical Inventory FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

## Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

| Classification according to<br>regulation (EC) No 1272/2008<br>[CLP] and amendments                       | Classification Procedure |
|---|--------------------------|
| Specific Target Organ Toxicity -<br>Single Exposure (Respiratory<br>Tract Irritation) Category 3,<br>H335 | Expert judgement         |
| Skin Corrosion/Irritation<br>Category 2, H315   | Expert judgement         |
| Serious Eye Damage/Eye<br>Irritation Category 2, H319   | Expert judgement         |

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