1 Identification

• Product identifier
• Trade name: ST AIA-PACK C-Peptide II CALIBRATOR SET 025383:
  Concerned item: ST AIA-PACK C-Peptide II CALIBRATOR (2-6)
• Relevant identified uses of the substance or mixture and uses advised against
  No further relevant information available.
• Application of the substance / the mixture In Vitro Diagnostics.
• Details of the supplier of the safety data sheet
  Manufacturer / Supplier:
  TOSOH CORPORATION
  3-8-2 Shiba, Minato-ku
  Tokyo 105 -8623
  JAPAN
  TOSOH BIOSCIENCE, INC.
  6000 Shoreline Ct.; Suite 101
  South San Francisco, CA94080
  USA
  Tel. : + 81 3 5427 5181
  Fax : + 81 3 5427 5220
  Phone : + 1 614 317 1909 or (800) 248 6764
  Fax : + 1 877 898 9883 or (800) 685 7595
  Information department:
  QA-RA: susan.koss@tosoh.com
  www.diagnostics.us.tosohbioscience.com
• Emergency telephone number: Poison Control Center: + 1 800 222 1222

2 Hazard(s) identification

• Classification of the substance or mixture
  GHS08 Health hazard
  Resp. Sens. 1  H334  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  Repr. 1A  H360  May damage fertility or the unborn child.
  GHS07
  Skin Irrit. 2  H315  Causes skin irritation.
  Eye Irrit. 2A  H319  Causes serious eye irritation.
  Skin Sens. 1  H317  May cause an allergic skin reaction.
• Classification according to Directive 67/548/EEC or Directive 1999/45/EC
  Irritant
  Irritating to eyes and skin. May cause sensitisation by skin contact.
• Information concerning particular hazards for human and environment:
  The product has to be labeled due to the calculation procedure of international guidelines.
• Classification system:
  The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
• Label elements
  GHS label elements The product is classified and labeled according to the Globally Harmonized System (GHS).
  Hazard pictograms

GHS08
• Signal word Danger
• Hazard-determining components of labeling:
  GENTAMYCIN SULFATE
  5-chloro-2-methyl-2H-isothiazol-3-one
• Hazard statements
  H315 Causes skin irritation.
  H319 Causes serious eye irritation.
  H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
(Contd. on page 2)
H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.

- **Precautionary statements**
  - P101 If medical advice is needed, have product container or label at hand.
  - P102 Keep out of reach of children.
  - P103 Read label before use.
  - P284 [In case of inadequate ventilation] wear respiratory protection.
  - P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
  - P280 Wear protective gloves.
  - P280 Wear eye protection / face protection.
  - P284 Wash thoroughly after handling.
  - P272 Contaminated work clothing must not be allowed out of the workplace.
  - P201 Obtain special instructions before use.
  - P202 Do not handle until all safety precautions have been read and understood.
  - P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P321 Specific treatment (see on this label).
  - P342+P311 If experiencing respiratory symptoms: Call a poison center/doctor.
  - P363 Wash contaminated clothing before reuse.
  - P304+P341 If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
  - P308+P313 If exposed or concerned: Get medical advice/attention.
  - P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
  - P337+P313 If eye irritation persists: Get medical advice/attention.
  - P302+P352 If on skin: Wash with plenty of water.
  - P362+P364 Take off contaminated clothing and wash before reuse.
  - P405 Store locked up.
  - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Classification system:**
  - **NFPA ratings (scale 0 - 4)**
    - Health = 1
    - Fire = 0
    - Reactivity = 0
  - **HMIS-ratings (scale 0 - 4)**
    - Health = 1
    - Fire = 0
    - Reactivity = 0

- **Other hazards**
  - **Results of PBT and vPvB assessment**
    - PBT: Not applicable.
    - vPvB: Not applicable.

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### 3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
  - **Description:** Mixture of the substances listed below with nonhazardous additions.
  - **Dangerous components:**
    - 57-50-1 sucrose, pure 25-50%
    - 1405-41-0 GENTAMYCIN SULFATE ≤ 2.5%
    - 26172-55-4 5-chloro-2-methyl-2H-isothiazol-3-one ≤ 2.5%

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### 4 First-aid measures

- **Description of first aid measures**
  - **After inhalation:**
    - Supply fresh air and to be sure call for a doctor.
    - In case of unconsciousness place patient stably in side position for transportation.
  - **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
  - **After eye contact:** Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
  - **After swallowing:** If symptoms persist consult doctor.
  - **Most important symptoms and effects, both acute and delayed**
    - No further relevant information available.

(Contd. on page 3)
5 Fire-fighting measures

- Extinguishing media
- Suitable extinguishing agents:
  CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- Special hazards arising from the substance or mixture: No further relevant information available.
- Advice for firefighters
- Protective equipment: No special measures required.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures: Not required.
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up: Pick up mechanically.
- Reference to other sections
  See Section 7 for information on safe handling.
  See Section 8 for information on personal protection equipment.
  See Section 13 for disposal information.

7 Handling and storage

- Precautions for safe handling: Store in cool, dry place in tightly closed receptacles.
- Information about protection against explosions and fires: No special measures required.
- Conditions for safe storage, including any incompatibilities
- Storage:
  - Requirements to be met by storerooms and receptacles: No special requirements.
  - Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Keep receptacle tightly sealed.
- Specific end use(s): No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see item 7.
- Control parameters

| Components with limit values that require monitoring at the workplace: |
|--------------------------|----------------|
| 57-50-1 sucrose, pure    |                |
| PEL                      | Long-term value: 15* 5** mg/m³ |
|                          | total dust **respirable fraction |
| REL                      | Long-term value: 10* 5** mg/m³   |
|                          | total dust **respirable fraction |
| TLV                      | Long-term value: 10 mg/m³        |

- Additional information: The lists that were valid during the creation were used as basis.

- Exposure controls
- Personal protective equipment:
  - General protective and hygienic measures:
    Keep away from foodstuffs, beverages and feed.
    Immediately remove all soiled and contaminated clothing.
    Wash hands before breaks and at the end of work.
    Avoid contact with the eyes and skin.
  - Breathing equipment: Not required.

(Contd. of page 4)
9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Spray dried powder
      - **Color:** Light beige
      - **Odor:** Odorless
      - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.
  - **Change in condition**
    - **Melting point/Melting range:** Undetermined.
    - **Boiling point/Boiling range:** Undetermined.
  - **Flash point:** Not applicable.
  - **Flammability (solid, gaseous):** Not determined.
  - **Ignition temperature:**
    - **Decomposition temperature:** Not determined.
  - **Auto igniting:** Product is not selfigniting.
  - **Danger of explosion:** Product does not present an explosion hazard.
  - **Explosion limits:**
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  - **Vapor pressure:** Not applicable.
  - **Density:** Not determined.
  - **Relative density**
  - **Vapour density**
  - **Evaporation rate**
  - **Solubility in / Miscibility with Water:** Soluble.
  - **Partition coefficient (n-octanol/water):** Not determined.
  - **Viscosity:**
    - **Dynamic:** Not applicable.

(Contd. of page 5)
10 Stability and reactivity

- Reactivity
- Chemical stability
  - Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
  - Possibility of hazardous reactions No dangerous reactions known.
  - Conditions to avoid No further relevant information available.
  - Incompatible materials: No further relevant information available.
  - Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- Information on toxicological effects
  - Acute toxicity:
  - Primary irritant effect:
    - on the skin: Irritant to skin and mucous membranes.
    - on the eye: Irritating effect.
  - Sensitization: Sensitization possible through skin contact.
  - Additional toxicological information:
    The product shows the following dangers according to internally approved calculation methods for preparations:
    - Irritant

Carcinogenic categories

- IARC (International Agency for Research on Cancer)
  None of the ingredients is listed.

- NTP (National Toxicology Program)
  None of the ingredients is listed.

- OSHA-Ca (Occupational Safety & Health Administration)
  None of the ingredients is listed.

12 Ecological information

- Toxicity
  - Aquatic toxicity: No further relevant information available.
  - Persistence and degradability: No further relevant information available.
  - Bioaccumulative potential: No further relevant information available.
  - Mobility in soil No further relevant information available.
  - Additional ecological information:
  - General notes:
    Water hazard class 1 (Self-assessment): slightly hazardous for water
    Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
  - Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.
  - Other adverse effects No further relevant information available.
13 Disposal considerations

- Waste treatment methods
  - **Recommendation:** Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packagings:
  - **Recommendation:** Disposal must be made according to official regulations.
  - **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

<table>
<thead>
<tr>
<th>UN-Number</th>
<th>DOT, ADR, ADN, IMDG, IATA</th>
<th>Void</th>
</tr>
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<tbody>
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<td>Transport hazard class(es)</td>
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<td>Class</td>
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<tr>
<td>Packing group</td>
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</tr>
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<td>Environmental hazards:</td>
<td>Marine pollutant:</td>
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</tr>
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<td>Special precautions for user</td>
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</tr>
<tr>
<td>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</td>
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<td></td>
</tr>
<tr>
<td>UN &quot;Model Regulation&quot;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture: Sara

| Section 355 (extremely hazardous substances): | None of the ingredients is listed. |
| Section 313 (Specific toxic chemical listings): | None of the ingredients is listed. |
| TSCA (Toxic Substances Control Act): | 57-50-1 sucrose, pure |
| | 7758-11-4 dipotassium hydrogenorthophosphate |
| | 25172-55-4 5-chloro-2-methyl-2H-isothiazol-3-one |
| | 2882-20-4 2-methyl-2H-isothiazol-3-one |

Proposition 65

- Chemicals known to cause cancer:
  - None of the ingredients is listed.

- Chemicals known to cause reproductive toxicity for females:
  - None of the ingredients is listed.

- Chemicals known to cause reproductive toxicity for males:
  - None of the ingredients is listed.

- Chemicals known to cause developmental toxicity:
  - None of the ingredients is listed.
### Carcinogenic categories

#### EPA (Environmental Protection Agency)
None of the ingredients is listed.

#### TLV (Threshold Limit Value established by ACGIH)
- 57-50-1 sucrose, pure
  - A4

#### NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients is listed.

### GHS label elements
The product is classified and labeled according to the Globally Harmonized System (GHS).

### Hazard pictograms

![GHS08](image)

### Signal word
Danger

### Hazard-determining components of labeling:
- GENTAMYCIN SULFATE
- 5-chloro-2-methyl-2H-isothiazol-3-one

### Hazard statements
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H317 May cause an allergic skin reaction.
- H360 May damage fertility or the unborn child.

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- **P362+P364** Take off contaminated clothing and wash it before reuse.
- **P405** Store locked up.
- **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

### Chemical safety assessment:
A Chemical Safety Assessment has not been carried out.

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### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The information contained herein is prepared based on the available information to Tosoh that is believed to be reliable; however the information is provided by Tosoh WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESSED OR IMPLIED, AS TO ITS COMPLETENESS, COMPREHENSIVENESS AND ACCURACY.

Since the conditions of handling, storage and disposal of this material are beyond our control, it is the responsibility of the user to determine whether the material is fit for a particular purpose and/or suitable for the user’s method of use or application, and to determine safe conditions for use of the material, and to assume full responsibility for loss, injury and expense arising out of or in connection with the use of material. NO REPRESENTATION OR WARRANTY, EXPRESSED OR IMPLIED, REGARDING THE MATERIAL DESCRIBED HEREBIN SHALL BE CREATED BY OR INFERRED FROM ANY STATEMENT OR OMISSION FROM THIS SDS.
When the revision of this SDS is received, please dispose of the old one.

**Date of preparation / last revision** 02/09/2015 / -

**Abbreviations and acronyms:**
- ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- AGIH: American Conference of Governmental Industrial Hygienists
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- NFPA: National Fire Protection Association (USA)
- HMIS: Hazardous Materials Identification System (USA)
- Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
- Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
- Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1
- Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
- Repr. 1A: Reproductive toxicity, Hazard Category 1A

(Contd. of page 7)