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| | | Revision nr : 1.1 |
| | | Issue date : 1/06/2020 |
| | Tosoh HPLC reagents | Supersedes : |
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Trade name/designation : Tosoh HPLC reagents
Product group : IN VITRO DIAGNOSTIC USE ONLY
Document no. : See annex

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

1.2.1. Relevant identified uses

Main use category : Professional uses
Use of the substance/mixture : Laboratory use

1.2.2. Uses advised against

No data available

1.3. Details of the supplier of the safety data sheet

Supplier

Tosoh Europe NV
Transportstraat 4
3980 Tessenderlo - Belgium
T +32 13 66 88 30 - F +32 13 66 47 49
info.raqa.eu@tosoh.com

Manufacturer

TOSOH CORPORATION
3-8-2 Shiba, Minato-ku
Tokyo 105-8623 - Japan
T + 81 3 5427 5181 - F + 81 3 5427 5220

1.4. Emergency telephone number

No data available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Not applicable.

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

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SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|-------------------|---|
| Additional advice | : First aider: Pay attention to self-protection!. Concerning personal protective equipment to use, see section 8. Never give anything by mouth to an unconscious person. In case of doubt or persistent symptoms, consult always a physician. Show this safety data sheet to the doctor in attendance. Treat symptomatically. |
| Inhalation | : Remove person to fresh air and keep comfortable for breathing. In case of doubt or persistent symptoms, consult always a physician. |
| Skin contact | : Take off contaminated clothing. Gently wash with plenty of soap and water. In case of doubt or persistent symptoms, consult always a physician. |
| Eyes contact | : Rinse immediately carefully and thoroughly with eye-bath or water. In case of doubt or persistent symptoms, consult always a physician. |
| Ingestion | : Rinse mouth thoroughly with water. Get medical advice/attention. |

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

| | |
|--------------|--|
| Inhalation | : Not expected to present a significant inhalation hazard under anticipated conditions of normal use. |
| Skin contact | : Not expected to present a significant skin hazard under anticipated conditions of normal use. |
| Eyes contact | : Not expected to present a significant eye contact hazard under anticipated conditions of normal use. |
| Ingestion | : Not expected to present a significant ingestion hazard under anticipated conditions of normal use. |

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

No data available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

| | |
|--------------------------------|---|
| Suitable extinguishing media | : carbon dioxide (CO ₂), powder, alcohol-resistant foam, water spray. |
| Unsuitable extinguishing media | : Strong water jet. |

5.2. Special hazards arising from the substance or mixture

| | |
|--|---|
| Specific hazards | : Not flammable. Heating causes rise in pressure with risk of bursting. |
| Hazardous decomposition products in case of fire | : Unknown. |

5.3. Advice for firefighters

| | |
|--------------------------------|---|
| Firefighting instructions | : Evacuate area. Use water spray or fog for cooling exposed containers. Contain the extinguishing fluids by bunding. Prevent fire fighting water from entering the environment. |
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. |
| Other information | : Do not allow run-off from fire-fighting to enter drains or water courses. Dispose of waste in accordance with environmental legislation. |

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

For non-emergency personnel : Evacuate unnecessary personnel. Keep upwind. Provide adequate ventilation. Wear recommended personal protective equipment. Concerning personal protective equipment to use, see section 8. Do not breathe vapours. Avoid contact with skin, eyes and clothing.

6.1.2. For emergency responders

For emergency responders : Ensure procedures and training for emergency decontamination and disposal are in place. Concerning personal protective equipment to use, see section 8.

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Stop leak if safe to do so. Dam up the liquid spill. Small quantities of liquid spill: take up in non-combustible absorbent material and shovel into container for disposal. Recover large spills by pumping (use an explosion proof or hand pump). Place in a suitable container for disposal in accordance with the waste regulations (see Section 13). This material and its container must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Provide adequate ventilation. Use personal protective equipment as required. Concerning personal protective equipment to use, see section 8. Do not breathe vapours. Avoid contact with skin, eyes and clothing. Take any precaution to avoid mixing with Incompatible materials, Refer to Section 10 on Incompatible Materials. Ensure proper process control to avoid excess waste discharge (temperature, concentration, pH, time). Avoid release to the environment.

Hygiene measures : Keep good industrial hygiene. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product. Keep away from food, drink and animal feedingstuffs. Remove contaminated clothes. Separate working clothes from town clothes. Launder separately. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry, cool and well-ventilated place. Do not store near or with any of the incompatible materials listed in section 10. Bund storage facilities to prevent soil and water pollution in the event of spillage.

Packaging materials : Keep only in the original container.

7.3. Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional information : Personal air monitoring :. Room air monitoring. Recommended monitoring procedures

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8.2. Exposure controls

| | |
|---------------------------------|--|
| Engineering measure(s) | : Provide adequate ventilation. Organisational measures to prevent /limit releases, dispersion and exposure. Safe handling: see section 7 . |
| Personal protective equipment | : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. |
| Hand protection | : Wear chemically resistant gloves (tested to EN374) . The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. |
| Eye protection | : Use suitable eye protection. (EN166): Safety glasses with side shields |
| Body protection | : Wear suitable protective clothing. |
| Respiratory protection | : In case of insufficient ventilation, wear suitable respiratory equipment. Half-face mask (EN 140). Full face mask (EN 136). Filter type: A (EN 141). The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used. (EN 137) |
| Thermal hazard protection | : Not required for normal conditions of use. Use dedicated equipment. |
| Environmental exposure controls | : Avoid release to the environment. Comply with applicable Community environmental protection legislation. |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|--|---------------------|
| Physical state | : No data available |
| Appearance | : No data available |
| Colour | : No data available |
| Odour | : No data available |
| Odour threshold | : No data available |
| pH | : No data available |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting / freezing point | : No data available |
| Freezing point | : No data available |
| Initial boiling point and boiling range | : No data available |
| Flash point | : Not applicable |
| Auto-ignition temperature | : Not applicable |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : Not applicable |
| Vapour pressure | : No data available |
| Vapour density | : No data available |
| Relative density | : No data available |
| Solubility | : No data available |
| Partition coefficient n-octanol/water | : No data available |
| Kinematic viscosity | : No data available |
| Dynamic viscosity | : No data available |
| Explosive properties | : Not applicable. |
| Oxidising properties | : Not applicable. |

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Explosive limits : Not applicable

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reference to other sections: 10.4 & 10.5.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Safe handling: see section 7.

10.5. Incompatible materials

Safe handling: see section 7.

10.6. Hazardous decomposition products

Reference to other sections: 5.2.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified (Based on available data, the classification criteria are not met)

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)

Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)

Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)

Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)

Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)

Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)

STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)

STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

Other information : Symptoms related to the physical, chemical and toxicological characteristics. For further information see section 4.

SECTION 12: Ecological information

12.1. Toxicity

Environmental properties : According to the criteria of the European classification and labelling system, the substance/the product has not to be labelled as "dangerous for the environment".

12.2. Persistence and degradability

| | |
|-------------------------------|--------------------|
| Tosoh HPLC reagents | |
| Persistence and degradability | No data available. |

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12.3. Bioaccumulative potential

| | |
|---------------------------------------|--------------------|
| Tosoh HPLC reagents | |
| Partition coefficient n-octanol/water | No data available |
| Bioaccumulative potential | No data available. |

12.4. Mobility in soil

| | |
|----------------------------|-------------------|
| Tosoh HPLC reagents | |
| Mobility in soil | No data available |

12.5. Results of PBT and vPvB assessment

| | |
|----------------------------|-------------------|
| Tosoh HPLC reagents | |
| Results of PBT assessment | No data available |

12.6. Other adverse effects

Other adverse effects : No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Avoid release to the environment. Dispose of empty containers and wastes safely. Safe handling: see section 7. Refer to manufacturer/supplier for information on recovery/recycling. Recycling is preferred to disposal or incineration. If recycling is not possible, eliminate in accordance with local valid waste disposal regulations. Handle contaminated packages in the same way as the substance itself. Dispose of contaminated materials in accordance with current regulations.

European waste catalogue (2001/573/EC, 75/442/EEC, 91/689/EEC) : Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

| ADR | IMDG | IATA | ADN | RID |
|---|----------------|----------------|----------------|----------------|
| 14.1. UN number | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.2. UN proper shipping name | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.4. Packing group | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.5. Environmental hazards | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| No supplementary information available | | | | |

14.6. Special precautions for user

Special precautions for user : No data available

- Overland transport

Not applicable

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- Transport by sea

Not applicable

- Air transport

Not applicable

- Inland waterway transport

Not applicable

- Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Code: IBC : No data available.

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.2. Chemical safety assessment

Not applicable

SECTION 16: Other information

Abbreviations and acronyms:

| | |
|--|--|
| | ABM = Algemene beoordelingsmethodiek |
| | ADN = Accord Européen relatif au Transport International des Marchandises Dangereuses par voie de Navigation du Rhin |
| | ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route |
| | CLP = Classification, Labelling and Packaging Regulation according to 1272/2008/EC |
| | IATA = International Air Transport Association |
| | IMDG = International Maritime Dangerous Goods Code |
| | LEL = Lower Explosive Limit/Lower Explosion Limit |
| | UEL = Upper Explosion Limit/Upper Explosive Limit |
| | REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals |
| | BTT = Breakthrough time (maximum wearing time) |
| | DMEL = Derived Minimal Effect level |
| | DNEL = Derived No Effect Level |
| | EC50 = Median Effective Concentration |
| | EL50 = Median effective level |
| | ErC50 = EC50 in terms of reduction of growth rate |
| | ErL50 = EL50 in terms of reduction of growth rate |
| | EWC = European waste catalogue |
| | LC50 = Median lethal concentration |
| | LD50 = Median lethal dose |
| | LL50 = Median lethal level |
| | NA = Not applicable |

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|--|--|
| | NOEC = No observed effect concentration |
| | NOEL: no-observed-effect level |
| | NOELR = No observed effect loading rate |
| | NOAEC = No observed adverse effect concentration |
| | NOAEL = No observed adverse effect level |
| | N.O.S. = Not Otherwise Specified |
| | OEL = Occupational Exposure Limits - Short Term Exposure Limits (STELs) |
| | PNEC = Predicted No Effect Concentration |
| | Quantitative structure-activity relationship (QSAR) |
| | STOT = Specific Target Organ Toxicity |
| | TWA = time weighted average |
| | VOC = Volatile organic compounds |
| | WGK = Wassergefährdungsklasse (Water Hazard Class under German Federal Water Management Act) |

Sources of key data used to compile the datasheet : Additional information. Supplier.

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ANNEX: Tosoh HPLC reagents

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EN

| Product code | Designation |
|---------------------|--|
| 0018767 | Hemoglobin A1c Calibrator Set |
| 0019544 | G7 HSi Elution Buffer No. 1 (S) |
| 0019545 | G7 HSi Elution Buffer No. 2 (S) |
| 0019546 | G7 HSi Elution Buffer No. 3 (S) |
| 0019551 | TSKgel G7 HSi |
| 0019552 | G7 Variant Elution Buffer HSi No. 1 (S) |
| 0019553 | G7 Variant Elution Buffer HSi No. 2 (S) |
| 0019554 | G7 Variant Elution Buffer HSi No. 3 (S) |
| 0019680 | TSKgel G7 Variant HSi |
| 0019681 | TSKgel G7 β -Thal. HSi |
| 0021472 | G7 β -Thalassemia Elution Buffer Kit |
| 0020019 | Hemoglobin F&A2 Calibrator |
| 0021498 | TSKgel G8 HSi |
| 0021800 | G8 HSi Elution Buffer No. 1 (S) |
| 0021801 | G8 HSi Elution Buffer No. 2 (S) |
| 0021802 | G8 HSi Elution Buffer No. 3 (S) |
| 0021848 | TSKgel G8 Variant HSi |
| 0021849 | G8 Variant Elution Buffer HSi No. 1 (S) |
| 0021850 | G8 Variant Elution Buffer HSi No. 2 (S) |
| 0021851 | G8 Variant Elution Buffer HSi No. 3 (S) |
| 0023528 | G8 HbA1c Calibrator Set (S) |
| 0021929 | TSKgel G8 β -Thal. HSi |
| 0021930 | G8 β -Thalassemia Elution Buffer kit |
| 0021931 | G8 β -Thalassemia Diluting Solution |
| 0021932 | G8 Hemoglobin F&A2 Calibrator |
| 0021974 | Hemoglobin A1c Control Set |
| 0023160 | TSKgel GX |
| 0023161 | GX Assay Kit |
| 0023510 | GX Elution Buffer No. 1 (S) |
| 0023511 | GX Elution Buffer No. 2 (S) |
| 0023512 | GX Elution Buffer No. 3 (S) |
| 0023478 | TSKgel G11 Variant |
| 0023479 | G11 Variant Elution Buffer No. 1 (S) |
| 0023480 | G11 Variant Elution Buffer No. 2 (S) |
| 0023481 | G11 Variant Elution Buffer No. 3 (S) |
| 0023502 | HbA1c Calibrator Set (S) |

| Product code | Designation |
|---------------------|---|
| 0023503 | HbA1c Diluting Solution |
| 0023504 | TSKgel G11 β -Thal. |
| 0023505 | G11 β -Thalassemia Elution Buffer No. 1 (S) |
| 0023506 | G11 β -Thalassemia Elution Buffer No. 2 (S) |
| 0023507 | G11 β -Thalassemia Elution Buffer No. 3 (S) |
| 0023508 | G11 F&A2 Calibrator Set |
| 0023550 | F&A2 Calibrator Set 2 |
| 0023855 | TSKgel G11 |
| 0023856 | G11 Elution Buffer No. 1 (S) |
| 0023857 | G11 Elution Buffer No. 2 (S) |
| 0023858 | G11 Elution Buffer No. 3 (S) |