



BD™ CS&T Beads

| Catalog No. | Tests |
|-------------|-------|
| 656504 | 50 |
| 656505 | 150 |

4/2016

23-14666-01



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1. INTENDED USE

BD™ CS&T beads are used on a BD flow cytometer to provide a standardized method to perform quality control of the instrument's optics, electronics, and fluidics, and for adjusting fluorescence compensation. On some BD instruments, BD CS&T beads are also used for adjusting detector voltages.

2. SUMMARY AND EXPLANATION

BD CS&T beads are a suspension of fluorospheres with uniform and stable size and fluorescence intensity. The beads are used for instrument quality control (QC) to characterize, track, and report performance measurements of supported flow cytometers. The cytometer's software displays current bead data in plots. Forward scatter (FSC) and side scatter (SSC) identify bead populations based on relative size.

The beads enable the software to measure detector performance and are used to measure the sensitivity of each fluorescence detector. Sensitivity is a measure of the cytometer's ability to resolve dimly stained cells. In addition, the beads are used to optimize the compensation settings each time instrument QC is run.

The software calculates the bright bead median, bright beads %rCV (robust coefficient of variation), and instrument sensitivity for FSC, SSC, and each fluorescence parameter, and compares them to expected values for the bead lot. The rCV measures cytometer alignment.

Daily measurements are automatically entered into Levey-Jennings plots. This allows you to monitor instrument

performance measurements over time and detect potential problems.

For the BD FACSLytic™ flow cytometer, BD CS&T beads are also used for adjusting detector voltages.

3. PRINCIPLES OF THE PROCEDURE

BD CS&T beads consist of equal quantities of 3-µm bright, 3-µm mid, and 2-µm dim polystyrene beads. The beads are dyed with fluorochromes. Fluorescence intensity is measured by the cytometer's detectors, processed by the electronics, and displayed and analyzed by the software.

The cytometer's software reads the bead lot file and calculates the target marker position or target fluorescence intensity for the beads. It then calculates the median and %rCV for bright beads.

4. REAGENTS

Reagents provided

BD CS&T beads are supplied in phosphate buffered saline (PBS) with bovine serum albumin (BSA) and 0.1% sodium azide as follows.

- Two 3-mL vials (50 tests)
- Six 3-mL vials (150 tests)

Each 3-mL vial contains sufficient beads to run 25 tests.

Reagents or materials required but not provided

- Disposable 12 × 75-mm capped polystyrene test tubes
- Filtered deionized (DI) water, to dilute the beads (BD FACSVia™ system only)
- BD FACSTream™ sheath fluid (Catalog No. 342003) or equivalent, to dilute the

beads (BD FACSLytic flow cytometer only)

Precautions

- Avoid exposing BD CS&T beads to direct light.
- Do not run BD CS&T beads without first diluting them with the proper diluent, as directed in the Procedure section.
- Do not use BD CS&T beads beyond their expiration date or beyond the day-of-use stability period after dilution. Beads used beyond their stability period begin to lose fluorescence, which can result in failed instrument QC.
- BD CS&T beads contain sodium azide as a preservative.

Storage and handling

- Store vials at 2°C–8°C and protect from light. Do not use after the expiration date shown on the label.

5. INSTRUMENTS

BD CS&T beads are for use on the following:

- BD FACSVia flow cytometer
- BD FACSLytic flow cytometer

6. PROCEDURE

Adding or importing bead lot information

Add bead lot ID information by scanning the bead lot file card in this kit.

If you do not have a barcode scanner, import bead lot ID information from the BD Biosciences website.

1. Visit bdbiosciences.com and select **Support** from the menu bar.

The **Services** web page opens.

- From **Top Support Links** in the right panel, select **Bead Lot Files** for the appropriate software.
- Follow the installation instructions on the website to download and import the appropriate bead lot file into the software.

Preparing a BD CS&T bead suspension

Carefully read the Precautions and Storage and handling statements in the Reagents section.

To prepare the BD CS&T beads for acquisition:

- Label a 12 × 75-mm capped polystyrene tube.
- Thoroughly mix the BD CS&T beads vial. Invert the vial 10 times, or vortex the vial at medium speed for 5–10 seconds.
- Prepare diluted beads according to Table 1 for the system and application you are running.

NOTE Avoid dripping the beads down the side of the tube when diluting them. This can lead to low bead counts during acquisition.

NOTE Do not dilute BD CS&T beads more than recommended.

- Vortex the tubes gently before use.

After dilution, the beads are stable for:

- 8 hours at 2°C–25°C on the BD FACSVia system
- 8 hours at 15°C–25°C, or 24 hours at 2°C–8°C on the BD FACSLytic flow cytometer.

NOTE Keep the diluted bead suspension protected from light. Some of the dyes used to manufacture the beads are light sensitive. Fluorescence levels can change if beads are exposed to direct light for longer than 20 minutes.

Table 1 BD CS&T beads preparation

| For... | | Add... | | | | |
|---------------------|------------|-------------------|---------------------|----------------------|-----------------|--|
| Task | Cytometer | Diluent | Diluent volume (µL) | Beads (No. of drops) | To tube labeled | How often |
| Instrument QC (IQC) | BD FACSVia | Filtered DI water | 500 | 2 | IQC | <ul style="list-style-type: none"> • Daily • When recommended by BD • To transfer bead lots |

Table 1 BD CS&T beads preparation

| For... | | Add... | | | | |
|-----------------------------------|--------------|--------------------------|---------------------|----------------------|-----------------|--|
| Task | Cytometer | Diluent | Diluent volume (µL) | Beads (No. of drops) | To tube labeled | How often |
| Performance QC ^a (PQC) | BD FACSLyric | BD FACSFlow sheath fluid | 500 | 2 | PQC | Daily |
| Update reference settings | | | 500 | 2 | Ref | Every 60 days |
| Bead lot transfer | | | 500 | 2 | Old lot | Before using a new lot |
| | | | 500 | 2 | New lot | |
| Characterization QC (CQC) | | | 1,000 | 4 | CQC | <ul style="list-style-type: none">• Every 6 months• After service or maintenance• When recommended by BD |
| Laser setup | | | 1,000 | 4 | Laser | As necessary |

a. Assay and tube settings are automatically updated when running performance QC.

Performing QC on the instrument using BD CS&T beads

Run instrument QC according to Table 1. See the instrument's Instructions For Use (IFU) for instructions on installing a bead lot file and performing any of the tasks outlined in Table 1.

7. RESULTS

Reviewing the Instrument QC Report

The Instrument QC Report contains the cytometer serial number, software version, BD CS&T bead lot information, bright bead median, bright beads %rCV, instrument sensitivity, and a pass or fail result for each parameter. A passing result for every parameter is required for instrument QC to pass. A failure for any parameter results in failure of instrument QC. For troubleshooting any QC messages, see the cytometer's IFU.

When using the BD FACSVia system, we recommend that you visually review the marker positions for scatter and bright

bead peaks and adjust the markers to surround the bead population, as necessary.

8. LIMITATIONS

- BD CS&T beads are intended for use with supported flow cytometers and their applicable software.
- BD CS&T beads should not be used to support quantitative fluorescence measurements in a flow cytometer.
- BD CS&T beads are for instrument QC and setup only.

9. PERFORMANCE CHARACTERISTICS

Performance of the BD CS&T beads was established by testing at BD Biosciences laboratories in San Jose, CA, USA.

Accuracy

Assay settings and tube settings were determined three times on one BD FACSLyric flow cytometer using one lot of BD CS&T beads. For each

fluorescence channel, the bright bead median fluorescence intensity (MFI) value (Actual), generated from the assay setup reports, was compared with the lot-specific bright bead MFI value (Target).

Accuracy was calculated as the percent difference between the bright bead MFI values of the Actual and the bright bead MFI values of the Target. See Table 2.

Table 2 Accuracy of cytometer setup using BD CS&T beads^a

| Parameter | Bright bead MFI | | % Difference |
|-----------------------|-----------------|---------|--------------|
| | Target | Actual | |
| FSC | 17,991 | 17,992 | 0.006 |
| SSC | 126,269 | 126,459 | 0.150 |
| FITC | 5,952 | 5,930 | -0.370 |
| PE | 12,719 | 12,700 | -0.149 |
| PerCP-Cy5.5 | 17,875 | 17,950 | 0.420 |
| PE-Cy7 | 16,237 | 16,250 | 0.080 |
| APC | 40,693 | 40,901 | 0.511 |
| APC-R700 ^b | 42,873 | 42,951 | 0.182 |
| APC-Cy7 | 85,174 | 85,397 | 0.262 |
| V450 ^a | 6,203 | 6,219 | 0.258 |
| V500-C ^a | 24,488 | 24,483 | -0.020 |
| BV605 ^a | 6,423 | 6,393 | -0.467 |

a. The data presented are from one run with LNW tube settings. Results from LW tube settings and the other runs were similar.

b. BD Horizon™ APC-R700, BD Horizon™ V450, BD Horizon™ V500-C, BD Horizon Brilliant™ Violet 605

Reproducibility

Instrument CQC was run on two BD FACSLyric flow cytometers. Two operators performed two runs of instrument PQC in duplicate on each instrument every day for a period of eight days using one lot of BD CS&T beads. Percent coefficient of variation (%CV) of

the median MFI values for each channel in high sensitivity and normal modes was used to verify reproducibility. See Table 3.

Table 3 Reproducibility of BD CS&T beads (Operator/instrument-to-operator/instrument, day-to-day, tube-to-tube)^a

| Parameter | %CV (High sensitivity) | %CV (Normal) |
|-------------|------------------------|--------------|
| FSC | 0.98 | 0.94 |
| SSC | 0.73 | 0.61 |
| FITC | 0.46 | 0.22 |
| PE | 0.41 | 0.24 |
| PerCP-Cy5.5 | 0.88 | 0.78 |
| PE-Cy7 | 1.28 | 1.23 |
| APC | 0.77 | 0.80 |
| APC-R700 | 0.60 | 0.61 |
| APC-Cy7 | 0.67 | 0.71 |
| V450 | 0.67 | 0.65 |
| V500-C | 0.53 | 0.52 |
| BV605 | 0.54 | 0.48 |

a. The data presented are from one instrument. Results from the other instrument were similar.

Repeatability

Instrument CQC and PQC were each performed ten times on two BD FACSLyric flow cytometers using two lots of BD CS&T beads to assess run-to-run repeatability. The %CV of the bright beads %rCV (resolution), Br (background), minimum linearity, maximum linearity, and SDen (standard deviation of the electronic noise) were used to verify run-to-run repeatability. See Table 4.

Table 4 Run-to-run repeatability of instrument CQC using BD CS&T beads^a

| Parameter | Bright bead rCV | | SD for Br <100 | %CV for Br ≥100 | SD for linearity minimum (<500) | %CV for linearity maximum | %CV for SDen |
|-------------|-----------------|---------------|----------------|-----------------|---------------------------------|---------------------------|--------------|
| | %CV of rCV | SD of rCV <2% | | | | | |
| FSC | NA | 0.07 | NA | NA | NA | NA | NA |
| SSC | NA | 0.03 | NA | NA | NA | NA | NA |
| FITC | NA | 0.05 | NA | 5.01 | 24.04 | 0.14 | 2.87 |
| PE | NA | 0.06 | NA | 4.97 | 23.84 | 0.15 | 3.09 |
| PerCP-Cy5.5 | 2.36 | NA | 2.67 | NA | 16.05 | 0.15 | 2.43 |
| PE-Cy7 | 0.88 | NA | 0 | NA | 11.55 | 0.20 | 1.86 |
| APC | NA | 0.07 | 1.42 | NA | 22.41 | 0.32 | 1.64 |
| APC-R700 | NA | 0.06 | 4.10 | NA | 29.58 | 0.26 | 2.14 |
| APC-Cy7 | NA | 0.09 | 26.64 | NA | 22.23 | 0.34 | 1.63 |
| V450 | 0.96 | NA | NA | 7.0 | 23.20 | 0.25 | 2.82 |
| V500-C | 1.58 | NA | NA | 6.34 | 46.83 | 0.32 | 2.25 |
| BV605 | 1.44 | NA | 2.67 | NA | 47.54 | 0.26 | 1.45 |

a. The data presented are for one lot of BD CS&T beads run on one instrument. Results for the remaining lots of beads and instruments were similar.

TROUBLESHOOTING

| Problem | Possible Causes | Solution |
|-------------------|--|--|
| No beads detected | Beads not mixed prior to diluting, beads are too dilute, there is debris in the bead suspension, incorrect beads were used, beads diluted in wrong diluent, beads exposed to light | <ol style="list-style-type: none"> 1. Vortex the bead vial. 2. Prepare a fresh suspension of beads. 3. Re-run instrument QC. |
| | Air bubbles in the flow cell or sheath filter | <ol style="list-style-type: none"> 1. For: <ul style="list-style-type: none"> • BD FACSVia, perform a backflush or SIP clean. • BD FACSLytic, perform a SIT flush. 2. Vortex the tube. 3. Re-run the tube. |
| | Sheath filter is not filled with fluid | <ul style="list-style-type: none"> • For BD FACSVia, perform the two-month maintenance procedure. • For BD FACSLytic, purge the sheath filter. |
| No beads detected | Clogs within the sample path and fluidic lines | <ol style="list-style-type: none"> 1. For: <ul style="list-style-type: none"> • BD FACSVia, perform a backflush or SIP clean. • BD FACSLytic, perform a SIT flush. 2. Vortex the tube. 3. Re-run the tube. |
| | Optics are out of alignment | <ul style="list-style-type: none"> • Contact BD Biosciences. |

| Problem | Possible Causes | Solution |
|--|---|--|
| Performance check completed with QC messages | Bead gates and markers are not properly adjusted to encapsulate results | For BD FACSVia, review instrument QC results and adjust the CS&T Bead gates for scatter and fluorescence. |
| | Values for any measurements used to check cytometer performance are not within parameters required for instrument QC to pass (see Reagents section) | Prepare a fresh suspension of beads and re-run instrument QC. <ol style="list-style-type: none"> 1. For: <ul style="list-style-type: none"> • BD FACSVia, perform the two-month maintenance procedure. • BD FACSLytic, perform the monthly cleaning procedure. 2. Re-run the tube. |
| | | Review the instrument QC report to determine whether the specific warnings impact the assay, then continue. |
| | | Contact BD Biosciences. |
| Performance check failure | Value(s) for any of the measurements used to check the cytometer performance are not within parameters required for instrument QC to pass (see Section 7) | <ol style="list-style-type: none"> 1. Prepare a fresh suspension of beads. 2. Re-run the performance check. Perform the monthly cleaning procedure. |
| | Improper ratio of 2 μm /3 μm beads due to inadequate mixing of beads | <ol style="list-style-type: none"> 1. Prepare a fresh suspension of beads. 2. Re-run the performance check. 3. If QC fails again, prepare beads from a new vial and be sure to thoroughly vortex the vial prior to use. See Preparing a BD CS&T bead suspension. |

For additional troubleshooting assistance, see the cytometer's IFU or contact your local BD Biosciences representative.

WARRANTY

Unless otherwise indicated in any applicable BD general conditions of sale for non-US customers, the following warranty applies to the purchase of these products.

THE PRODUCTS SOLD HEREUNDER ARE WARRANTED ONLY TO CONFORM TO THE QUANTITY AND CONTENTS STATED ON THE LABEL OR IN THE PRODUCT LABELING AT THE TIME OF DELIVERY TO THE CUSTOMER. BD DISCLAIMS HEREBY ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE AND NONINFRINGEMENT. BD'S SOLE LIABILITY IS LIMITED TO EITHER REPLACEMENT OF THE PRODUCTS OR REFUND OF THE PURCHASE PRICE. BD IS NOT LIABLE FOR PROPERTY DAMAGE OR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING PERSONAL INJURY, OR ECONOMIC LOSS, CAUSED BY THE PRODUCT.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Becton, Dickinson and Company (BD)
7 Loveton Circle
Sparks
Maryland
21152
USA

Holds Certificate Number:

MD 595740

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents, prepared media products, dehydrated culture media, collection and transport, antimicrobial susceptibility tests, sample preparation, cytology devices, cytopathology auto-imaging devices with computerized microscopy, telepathology devices, lab automation, ancillary devices and instrument software for use in the screening and diagnosis of diseases, transmissible and sexually transmissible agents, and autoimmune status.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2013-03-14

Latest Revision Date: 2021-10-08

Effective Date: 2021-10-11

Expiry Date: 2024-10-10

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Certificate No: **MD 595740**

| Location | Registered Activities |
|--|--|
| Becton, Dickinson and Company (BD) 7 Loveton Circle Sparks Maryland 21152 USA | The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents, prepared media products, dehydrated culture media, collection and transport, antimicrobial susceptibility tests, sample preparation, cytology devices, cytopathology auto-imaging devices with computerized microscopy, telepathology devices, lab automation, ancillary devices and instrument software for use in the screening and diagnosis of diseases, transmissible and sexually transmissible agents, and autoimmune status. |
| Becton Dickinson and Company (BD) BD Diagnostic Systems 52/54 Loveton Circle Sparks Maryland 21152 USA | The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, prepared media products, dehydrated culture media, collection and transport, sample preparation. |
| Becton Dickinson and Company (BD) BD Diagnostic Systems 39 Loveton Circle Sparks Maryland 21152 USA | The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, dehydrated culture media, collection and transport, sample preparation. |
| Becton Dickinson and Company (BD) BD Diagnostic Systems 250 Schilling Circle Cockeysville Maryland 21030 USA | The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, prepared media products, collection and transport, antimicrobial susceptibility tests, sample preparation. |

Original Registration Date: 2013-03-14

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Effective Date: 2021-10-11

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SAFETY DATA SHEET

1. Identification

Product identifier

| Product No.: | Product name: | Common name(s), synonym(s) |
|--------------|---------------|----------------------------|
| 340345 | BD® FACSClean | No data available |

Other means of identification

SDS number: 088100018880

Recommended use and restriction on use

Recommended use: Scientific and Industrial laboratory use.

Restrictions on use: None known.

Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name: Becton, Dickinson and Company - BD Biosciences
Address: 2350 Qume Drive
95131 San Jose, CA USA
Telephone: 1 877 232 8995 or 1 800 424 9300
Fax:
Contact Person: Technical Services
E-mail: ResearchApplications@bd.com or ClinicalApplications@bd.com

Emergency telephone number: CHEMTREC 1 800 424 9300

2. Hazard(s) identification

Hazard Classification

Health Hazards

| | |
|-----------------------------------|-------------|
| Skin Corrosion/Irritation | Category 2 |
| Serious Eye Damage/Eye Irritation | Category 2A |

Environmental Hazards

| | |
|--|------------|
| Acute hazards to the aquatic environment | Category 2 |
| Chronic hazards to the aquatic environment | Category 3 |

Label Elements

Hazard Symbol:



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Signal Word: Warning

Hazard Statement: H315: Causes skin irritation.
H319: Causes serious eye irritation.
H401: Toxic to aquatic life.
H412: Harmful to aquatic life with long lasting effects.

Precautionary Statements

Prevention: P264: Wash thoroughly after handling.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P273: Avoid release to the environment.

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.
P337+P313: If eye irritation persists: Get medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of water/...
P332+P313: If skin irritation occurs: Get medical advice/attention.
P321: Specific treatment (see on this label).
P362: Take off contaminated clothing.

Disposal: P501: Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

Other hazards which do not result in GHS classification: None.

3. Composition/information on ingredients

Mixtures

| Chemical Identity | Common name and synonyms | CAS number | Content in percent (%) [*] |
|--------------------------------------|--------------------------|------------|-------------------------------------|
| Hypochlorous acid, sodium salt (1:1) | No data available. | 7681-52-9 | 1% |
| Sodium hydroxide (Na(OH)) | No data available. | 1310-73-2 | 0.8% |

^{*} All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures



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| | |
|-----------------------------|---|
| General information: | Causes serious eye irritation. Causes skin irritation. |
| Ingestion: | DO NOT induce vomiting. Get medical attention immediately. |
| Inhalation: | Provide fresh air, warmth and rest, preferably in comfortable upright sitting position. |
| Skin Contact: | Promptly flush contaminated skin with soap or mild detergent and water. Promptly remove clothing if penetrated and flush the skin with water. |
| Eye contact: | Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention. |

Most important symptoms/effects, acute and delayed

| | |
|------------------|--|
| Symptoms: | No data available. |
| Hazards: | Causes serious eye irritation. Causes skin irritation. |

Indication of immediate medical attention and special treatment needed

| | |
|-------------------|--|
| Treatment: | Get medical attention if symptoms occur. |
|-------------------|--|

| |
|----------------------------------|
| 5. Fire-fighting measures |
|----------------------------------|

| | |
|------------------------------|---|
| General Fire Hazards: | Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate. Use water to keep fire exposed containers cool and disperse vapors. |
|------------------------------|---|

Suitable (and unsuitable) extinguishing media

| | |
|--|---|
| Suitable extinguishing media: | Use fire-extinguishing media appropriate for surrounding materials. |
| Unsuitable extinguishing media: | Avoid water in straight hose stream; will scatter and spread fire. |

| | |
|--|--|
| Specific hazards arising from the chemical: | Fire or excessive heat may produce hazardous decomposition products. |
|--|--|

Special protective equipment and precautions for firefighters

| | |
|--|--|
| Special fire fighting procedures: | No unusual fire or explosion hazards noted. |
| Special protective equipment for fire-fighters: | Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA. |



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6. Accidental release measures

| | |
|---|---|
| Personal precautions, protective equipment and emergency procedures: | Contact local authorities in case of spillage to drain/aquatic environment. Ensure suitable personal protection (including respiratory protection) during removal of spillages in a confined area. |
| Methods and material for containment and cleaning up: | Absorb spillage with suitable absorbent material. Prevent runoff from entering drains, sewers, or streams. See Section 8 of the SDS for Personal Protective Equipment. For waste disposal, see section 13 of the SDS. |
| Environmental Precautions: | Avoid release to the environment. |

7. Handling and storage

| | |
|--|---|
| Precautions for safe handling: | When using do not eat, drink or smoke. Read and follow manufacturer's recommendations. Use personal protective equipment as required. |
| Conditions for safe storage, including any incompatibilities: | Store in a cool, dry place. Keep container tightly closed. Keep from contact with oxidizing materials. |

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

| Chemical Identity | Type | Exposure Limit Values | Source |
|--|-----------|-----------------------|--|
| Sodium hydroxide (Na(OH)) | Ceiling | 2 mg/m ³ | US. OSHA Table Z-1-A (29 CFR 1910.1000), as amended (1989) |
| | Ceiling | 2 mg/m ³ | US. Tennessee. OELs. Occupational Exposure Limits, Table Z1A, as amended (06 2008) |
| Sodium hydroxide (Na(OH)) - Particulate. | AN ESL | 2 µg/m ³ | US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality), as amended (07 2011) |
| | ST ESL | 20 µg/m ³ | US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality), as amended (07 2011) |
| Sodium hydroxide (Na(OH)) | Ceiling | 2 mg/m ³ | US. California Code of Regulations, Title 8, Section 5155. Airborne Contaminants, as amended (08 2010) |
| | Ceiling | 2 mg/m ³ | US. ACGIH Threshold Limit Values, as amended (12 2010) |
| | Ceil_Time | 2 mg/m ³ | US. NIOSH: Pocket Guide to Chemical Hazards, as amended (2005) |
| | PEL | 2 mg/m ³ | US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000), as amended (02 2006) |
| | IDLH | 10 mg/m ³ | US. NIOSH. Immediately Dangerous to Life or Health (IDLH) Values, as amended (10 2017) |

| | |
|---|---|
| Appropriate Engineering Controls | No special requirements under ordinary conditions of use and with adequate ventilation. |
|---|---|



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Individual protection measures, such as personal protective equipment

| | |
|--------------------------------|---|
| General information: | 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. |
| Eye/face protection: | Wear safety glasses with side shields (or goggles). |
| Skin Protection | |
| Hand Protection: | Chemical resistant gloves Suitable gloves can be recommended by the glove supplier. Wash hands after contact. |
| Other: | Wear a lab coat or similar protective clothing. |
| Respiratory Protection: | If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. |
| Hygiene measures: | Observe good industrial hygiene practices. |

9. Physical and chemical properties

Appearance

| | |
|---|--------------------|
| Physical state: | liquid |
| Form: | Aqueous Solution |
| Color: | Colorless |
| Odor: | Characteristic |
| Odor threshold: | No data available. |
| pH: | No data available. |
| Melting point/freezing point: | No data available. |
| Initial boiling point and boiling range: | No data available. |
| Flash Point: | No data available. |
| Evaporation rate: | No data available. |
| Flammability (solid, gas): | No data available. |

Upper/lower limit on flammability or explosive limits

| | |
|--|--------------------|
| Flammability limit - upper (%): | No data available. |
| Flammability limit - lower (%): | No data available. |
| Explosive limit - upper (%): | No data available. |
| Explosive limit - lower (%): | No data available. |
| Vapor pressure: | No data available. |
| Vapor density: | No data available. |
| Relative density: | No data available. |
| Solubility(ies) | |
| Solubility in water: | No data available. |
| Solubility (other): | No data available. |



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| | |
|---|--------------------|
| Partition coefficient (n-octanol/water): | No data available. |
| Auto-ignition temperature: | No data available. |
| Decomposition temperature: | No data available. |
| Viscosity: | No data available. |

10. Stability and reactivity

| | |
|--|---|
| Reactivity: | Product is not reactive under normal conditions and recommended use. |
| Chemical Stability: | Material is stable under normal conditions. |
| Possibility of hazardous reactions: | Material is stable under normal conditions. |
| Conditions to avoid: | Avoid exposure to high temperatures or direct sunlight. |
| Incompatible Materials: | Water reactive material. Metals. Avoid contact with oxidizers or reducing agents. Avoid contact with acids. |
| Hazardous Decomposition Products: | Contact with acids liberates toxic gas. Stable; however, may decompose if heated. |

11. Toxicological information

Information on likely routes of exposure

| | |
|----------------------|--------------------|
| Ingestion: | No data available. |
| Inhalation: | No data available. |
| Skin Contact: | No data available. |
| Eye contact: | No data available. |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|----------------------|--------------------|
| Ingestion: | No data available. |
| Inhalation: | No data available. |
| Skin Contact: | No data available. |
| Eye contact: | No data available. |

Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

| | |
|----------------------|--------------------|
| Oral Product: | No data available. |
|----------------------|--------------------|



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Dermal

Product: No data available.

Inhalation

Product: ATEmix: 525 mg/l

Repeated dose toxicity

Product: No data available.

Specified substance(s):

Hypochlorous acid,
sodium salt (1:1) LOAEL (Rat(Female), Oral, 90 d): > 24.9 mg/kg Oral Experimental result,
Key study
LOAEL (Mouse(Female, Male), Oral, 90 d): > 34.4 mg/kg Oral Experimental
result, Key study
LOAEL (Rat(Female, Male), Inhalation): <= 3 mg/m3 Inhalation Read-across
from supporting substance (structural analogue or surrogate), Supporting
study
LOAEL (Rat(Male), Oral, 90 d): > 16.7 mg/kg Oral Experimental result, Key
study
NOAEL (Rat(Female), Oral, 90 d): >= 24.9 mg/kg Oral Experimental result,
Key study

Skin Corrosion/Irritation

Product: No data available.

Specified substance(s):

Hypochlorous acid,
sodium salt (1:1) in vivo (Rabbit): Irritating Experimental result, Supporting study

Sodium hydroxide
(Na(OH)) in vivo (Rabbit): Irritating Experimental result, Weight of Evidence study
in vivo (Rabbit): Slightly irritating Experimental result, Weight of Evidence
study

Serious Eye Damage/Eye Irritation

Product: No data available.

Specified substance(s):

Sodium hydroxide
(Na(OH)) in vivo (Rabbit, 1 d): Mild irritant OECD GHS
in vivo (Rabbit, 2 d): Mild irritant OECD GHS
in vivo (Rabbit, 3 d): Mild irritant OECD GHS
in vivo (Rabbit, 4 d): Mild irritant OECD GHS

Respiratory or Skin Sensitization

Product: No data available.



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Specified substance(s):

Hypochlorous acid,
sodium salt (1:1)

Skin sensitization:, in vivo (Guinea pig): Non sensitising

Carcinogenicity

Product:

No data available.

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:

No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:

No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050), as amended:

No carcinogenic components identified

Germ Cell Mutagenicity

In vitro

Product:

No data available.

In vivo

Product:

No data available.

Reproductive toxicity

Product:

No data available.

Specific Target Organ Toxicity - Single Exposure

Product:

No data available.

Specific Target Organ Toxicity - Repeated Exposure

Product:

No data available.

Aspiration Hazard

Product:

No data available.

Other effects:

No data available.

12. Ecological information

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish

Product:

Toxic to aquatic organisms.



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Aquatic Invertebrates

Product: Toxic to aquatic organisms.

Chronic hazards to the aquatic environment:

Fish

Product: Substantial amounts of the product may lead to a local change in acidity in small water systems which may have adverse effects on aquatic organisms.

Aquatic Invertebrates

Product: Aquatic plants and animals may be adversely affected if they have direct contact with this material.

Toxicity to Aquatic Plants

Product: No data available.

Persistence and Degradability

Biodegradation

Product: The subject product is expected to biodegrade and is not expected to persist for long periods in an aquatic environment.

BOD/COD Ratio

Product: No data available.

Bioaccumulative potential

Bioconcentration Factor (BCF)

Product: No data available.

Partition Coefficient n-octanol / water (log Kow)

Product: No data available.

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments

Hypochlorous acid, sodium salt (1:1) No data available.

Sodium hydroxide (Na(OH)) No data available.

Other adverse effects: None known.

13. Disposal considerations

General information: This material and its container must be disposed of as hazardous waste. Dispose of waste and residues in accordance with local authority requirements.



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Disposal instructions: Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

Contaminated Packaging: No data available.

14. Transport information

| | |
|-------------------------------|----------------|
| DOTUN Number: | Not regulated. |
| UN Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es) | |
| Class: | Not regulated. |
| Label(s): | Not regulated. |
| Packing Group: | Not regulated. |
| Marine Pollutant: | Not regulated. |
| Limited quantity | Not regulated. |
| Excepted quantity | Not regulated. |
| Special precautions for user: | Not regulated. |

IMDG

| | |
|-------------------------------|----------------|
| UN Number: | Not regulated. |
| UN Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es) | |
| Class: | Not regulated. |
| Subsidiary risk: | Not regulated. |
| EmS No.: | Not regulated. |
| Packing Group: | Not regulated. |
| Environmental Hazards | |
| Marine Pollutant: | Not regulated. |
| Special precautions for user: | Not regulated. |

IATA

| | |
|-------------------------------|----------------|
| UN Number: | Not regulated. |
| Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es): | |
| Class: | Not regulated. |
| Subsidiary risk: | Not regulated. |
| Packing Group: | Not regulated. |
| Environmental Hazards | |
| Marine pollutant: | Not regulated. |
| Special precautions for user: | Not regulated. |

15. Regulatory information

US Federal Regulations



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TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

None present or none present in regulated quantities.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050), as amended

None present or none present in regulated quantities.

CERCLA Hazardous Substance List (40 CFR 302.4):

| <u>Chemical Identity</u> | <u>Reportable quantity</u> |
|--------------------------------------|----------------------------|
| Hypochlorous acid, sodium salt (1:1) | 100 lbs. |
| Sodium hydroxide (Na(OH)) | 1000 lbs. |

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate (Acute) Health Hazards
Skin Corrosion or Irritation
Serious eye damage or eye irritation

SARA 302 Extremely Hazardous Substance

None present or none present in regulated quantities.

SARA 304 Emergency Release Notification

None present or none present in regulated quantities.

SARA 311/312 Hazardous Chemical

| <u>Chemical Identity</u> | <u>Threshold Planning Quantity</u> |
|--------------------------|------------------------------------|
|--------------------------|------------------------------------|

SARA 313 (TRI Reporting)

None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)

| <u>Chemical Identity</u> | <u>Reportable quantity</u> |
|--------------------------------------|--------------------------------|
| Hypochlorous acid, sodium salt (1:1) | Reportable quantity: 100 lbs. |
| Sodium hydroxide (Na(OH)) | Reportable quantity: 1000 lbs. |

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):

None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65

No ingredient requiring a warning under CA Prop 65.

US. New Jersey Worker and Community Right-to-Know Act

| <u>Chemical Identity</u> |
|--------------------------------------|
| Hypochlorous acid, sodium salt (1:1) |



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US. Massachusetts RTK - Substance List

No ingredient regulated by MA Right-to-Know Law present.

US. Pennsylvania RTK - Hazardous Substances

No ingredient regulated by PA Right-to-Know Law present.

US. Rhode Island RTK

No ingredient regulated by RI Right-to-Know Law present.

| |
|--|
| 16. Other information, including date of preparation or last revision |
|--|

Issue Date: 05/06/2020

Version #: 3.2

Revision Information:

Source of information: European Chemicals Agency (ECHA): Information on Chemicals.

Further Information: No data available.

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SAFETY DATA SHEET

1. Identification

Product identifier

| Product No.: | Product name: | Common name(s), synonym(s) |
|--------------|---------------------|----------------------------|
| 660584 | BD™ Sheath Additive | |

Other means of identification

SDS number: 088100200355

Recommended use and restriction on use

Recommended use: Reserved for industrial and professional use.

Restrictions on use: None known.

Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name: Becton, Dickinson and Company - BD Biosciences
Address: 2350 Qume Drive
95131 San Jose, CA USA
Telephone: 1 877 232 8995 or 1 800 424 9300
Fax:
Contact Person: Technical Services
E-mail: ResearchApplications@bd.com or ClinicalApplications@bd.com

Emergency telephone number: ChemTrec 1 800 424 9300

2. Hazard(s) identification

Hazard Classification

Not classified

Label Elements

Hazard Symbol: No symbol
Signal Word: No signal word.
Hazard Statement: Not applicable
Precautionary Statements Not applicable

Other hazards which do not result in GHS classification: None.

3. Composition/information on ingredients



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Mixtures

| Chemical Identity | Common name and synonyms | CAS number | Content in percent (%)* |
|-----------------------|--------------------------|------------|-------------------------|
| Sodium fluoride (NaF) | | 7681-49-4 | 0.82% |

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

| | |
|-----------------------------|---|
| General information: | Get medical attention if symptoms occur. |
| Ingestion: | Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person. |
| Inhalation: | Provide fresh air, warmth and rest, preferably in comfortable upright sitting position. |
| Skin Contact: | Wash contact areas with soap and water. Remove contaminated clothing. Launder contaminated clothing before reuse. |
| Eye contact: | Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. |

Most important symptoms/effects, acute and delayed

Symptoms: No data available.

Indication of immediate medical attention and special treatment needed

Treatment: No data available.

5. Fire-fighting measures

General Fire Hazards: Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate. Use water spray to keep fire-exposed containers cool.

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media: Not applicable

Specific hazards arising from the chemical: Fire or excessive heat may produce hazardous decomposition products.

Special protective equipment and precautions for firefighters



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Special fire fighting procedures: No unusual fire or explosion hazards noted.

Special protective equipment for fire-fighters: Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: Contact local authorities in case of spillage to drain/aquatic environment. Ensure suitable personal protection (including respiratory protection) during removal of spillages in a confined area.

Methods and material for containment and cleaning up: Absorb spillage with suitable absorbent material. Prevent runoff from entering drains, sewers, or streams. See Section 8 of the SDS for Personal Protective Equipment. For waste disposal, see section 13 of the SDS.

Environmental Precautions: Avoid release to the environment.

7. Handling and storage

Precautions for safe handling: When using do not eat, drink or smoke. Read and follow manufacturer's recommendations. Use personal protective equipment as required.

Conditions for safe storage, including any incompatibilities: Store in a cool, dry place. Keep container tightly closed.

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

| Chemical Identity | Type | Exposure Limit Values | Source |
|-------------------------------|------|-----------------------|---|
| Sodium fluoride (NaF) - as F | TWA | 2.5 mg/m ³ | US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989) |
| | TWA | 2.5 mg/m ³ | US. ACGIH Threshold Limit Values (12 2010) |
| | REL | 2.5 mg/m ³ | US. NIOSH: Pocket Guide to Chemical Hazards (2005) |
| | PEL | 2.5 mg/m ³ | US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006) |
| Sodium fluoride (NaF) - Dust. | TWA | 2.5 mg/m ³ | US. OSHA Table Z-2 (29 CFR 1910.1000) (02 2006) |



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Biological Limit Values

| Chemical Identity | Exposure Limit Values | Source |
|--|-----------------------|---------------------|
| Sodium fluoride (NaF) (Fluoride: Sampling time: Prior to shift.) | 2 mg/l (Urine) | ACGIH BEI (03 2013) |
| Sodium fluoride (NaF) (Fluoride: Sampling time: End of shift.) | 3 mg/l (Urine) | ACGIH BEI (03 2013) |

Appropriate Engineering Controls

No special requirements under ordinary conditions of use and with adequate ventilation.

Individual protection measures, such as personal protective equipment

| | |
|--------------------------------|---|
| General information: | Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing to remove contaminants. Discard contaminated footwear that cannot be cleaned. |
| Eye/face protection: | Wear safety glasses with side shields (or goggles). |
| Skin Protection | |
| Hand Protection: | Chemical resistant gloves Suitable gloves can be recommended by the glove supplier. Wash hands after contact. |
| Other: | Wear a lab coat or similar protective clothing. |
| Respiratory Protection: | If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. |
| Hygiene measures: | Observe good industrial hygiene practices. |

9. Physical and chemical properties

Appearance

| | |
|---|--------------------|
| Physical state: | liquid |
| Form: | No data available. |
| Color: | Clear |
| Odor: | Odorless |
| Odor threshold: | No data available. |
| pH: | 7.0 - 9.0 |
| Melting point/freezing point: | No data available. |
| Initial boiling point and boiling range: | No data available. |
| Flash Point: | No data available. |
| Evaporation rate: | No data available. |



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Flammability (solid, gas): No data available.

Upper/lower limit on flammability or explosive limits

Flammability limit - upper (%): No data available.

Flammability limit - lower (%): No data available.

Explosive limit - upper (%): No data available.

Explosive limit - lower (%): No data available.

Vapor pressure: No data available.

Vapor density: No data available.

Relative density: No data available.

Solubility(ies)

Solubility in water: Soluble

Solubility (other): No data available.

Partition coefficient (n-octanol/water): No data available.

Auto-ignition temperature: No data available.

Decomposition temperature: No data available.

Viscosity: No data available.

10. Stability and reactivity

Reactivity: Stable under normal temperature conditions and recommended use.

Chemical Stability: Material is stable under normal conditions.

Possibility of hazardous reactions: Not determined.

Conditions to avoid: Avoid exposure to high temperatures or direct sunlight.

Incompatible Materials: Metals. Water reactive material.

Hazardous Decomposition Products: Stable; however, may decompose if heated.

11. Toxicological information

General information: No data on possible toxicity effects have been found.

Information on likely routes of exposure

Ingestion: No harmful effects expected in amounts likely to be ingested by accident.

Inhalation: Limited inhalation hazard at normal work temperatures.

Skin Contact: Negligible irritation to skin at ambient temperatures.

Eye contact: Elevated temperatures or mechanical action may form vapors, mist, or fumes which may be irritating to the eyes, nose, throat, or lungs.



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Symptoms related to the physical, chemical and toxicological characteristics

Ingestion: No data available.

Inhalation: No data available.

Skin Contact: No data available.

Eye contact: No data available.

Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral

Product: ATEmix: 13,902.44 mg/kg

Dermal

Product: No data available.

Inhalation

Product: No data available.

Repeated dose toxicity

Product: No data available.

Skin Corrosion/Irritation

Product: No data available.

Serious Eye Damage/Eye Irritation

Product: No data available.

Specified substance(s):

Sodium fluoride (NaF) Possibly Irritating

Respiratory or Skin Sensitization

Product: No data available.

Specified substance(s):

Sodium fluoride (NaF) Skin sensitization:, in vivo (Guinea pig): Non sensitising

Carcinogenicity

Product: No data available.



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IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:

No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:

No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):

No carcinogenic components identified

Germ Cell Mutagenicity

In vitro

Product: No data available.

In vivo

Product: No data available.

Reproductive toxicity

Product: No data available.

Specific Target Organ Toxicity - Single Exposure

Product: No data available.

Specific Target Organ Toxicity - Repeated Exposure

Product: No data available.

Aspiration Hazard

Product: No data available.

Other effects: No data available.

| |
|-----------------------------------|
| 12. Ecological information |
|-----------------------------------|

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish

Product: No negative effects on the aquatic environment are known.

Aquatic Invertebrates

Product: No negative effects on the aquatic environment are known.

Chronic hazards to the aquatic environment:

Fish

Product: No negative effects on the aquatic environment are known.



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Aquatic Invertebrates

Product: No negative effects on the aquatic environment are known.

Toxicity to Aquatic Plants

Product: No negative effects on the aquatic environment are known.

Persistence and Degradability

Biodegradation

Product: Expected to be readily biodegradable.

BOD/COD Ratio

Product: No data available.

Bioaccumulative potential

Bioconcentration Factor (BCF)

Product: No data available.

Specified substance(s):

Sodium fluoride (NaF) Bioconcentration Factor (BCF): 30 Aquatic sediment Other, Key study
Bioconcentration Factor (BCF): 7.5 Aquatic sediment Other, Key study
Bioconcentration Factor (BCF): 27 - 62 Aquatic sediment Other, Key study
Bioconcentration Factor (BCF): 53 - 58 Aquatic sediment Other, Key study
Bioconcentration Factor (BCF): < 2 Aquatic sediment Other, Key study

Partition Coefficient n-octanol / water (log Kow)

Product: No data available.

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments

Sodium fluoride (NaF) No data available.

Other adverse effects: The product is not expected to be hazardous to the environment.

13. Disposal considerations

General information: Dispose of waste and residues in accordance with local authority requirements.

Disposal instructions: Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

Contaminated Packaging: No data available.



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14. Transport information

| | |
|-------------------------------|----------------|
| DOTUN Number: | Not regulated. |
| UN Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es) | |
| Class: | Not regulated. |
| Label(s): | Not regulated. |
| Packing Group: | Not regulated. |
| Marine Pollutant: | Not regulated. |
| Limited quantity | Not regulated. |
| Excepted quantity | Not regulated. |
| Special precautions for user: | Not regulated. |

IMDG

| | |
|-------------------------------|----------------|
| UN Number: | Not regulated. |
| UN Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es) | |
| Class: | Not regulated. |
| Subsidiary risk: | Not regulated. |
| EmS No.: | Not regulated. |
| Packing Group: | Not regulated. |
| Environmental Hazards | |
| Marine Pollutant: | Not regulated. |
| Special precautions for user: | Not regulated. |

IATA

| | |
|-------------------------------|----------------|
| UN Number: | Not regulated. |
| Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es): | |
| Class: | Not regulated. |
| Subsidiary risk: | Not regulated. |
| Packing Group: | Not regulated. |
| Environmental Hazards | |
| Marine pollutant: | Not regulated. |
| Special precautions for user: | Not regulated. |

15. Regulatory information

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

None present or none present in regulated quantities.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

None present or none present in regulated quantities.



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CERCLA Hazardous Substance List (40 CFR 302.4):

| <u>Chemical Identity</u> | <u>Reportable quantity</u> |
|--------------------------|----------------------------|
| Sodium fluoride (NaF) | 1000 lbs. |

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Not classified
Not classified

SARA 302 Extremely Hazardous Substance

None present or none present in regulated quantities.

SARA 304 Emergency Release Notification

| <u>Chemical Identity</u> | <u>Reportable quantity</u> |
|--------------------------|----------------------------|
| Sodium fluoride (NaF) | 1000 lbs. |

SARA 311/312 Hazardous Chemical

| <u>Chemical Identity</u> | <u>Threshold Planning Quantity</u> |
|--------------------------|------------------------------------|
| Sodium fluoride (NaF) | 10000 lbs |

SARA 313 (TRI Reporting)

None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)

| <u>Chemical Identity</u> | <u>Reportable quantity</u> |
|--------------------------|--------------------------------|
| Sodium fluoride (NaF) | Reportable quantity: 1000 lbs. |

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):

None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65

No ingredient requiring a warning under CA Prop 65.

US. New Jersey Worker and Community Right-to-Know Act

No ingredient regulated by NJ Right-to-Know Law present.

US. Massachusetts RTK - Substance List

No ingredient regulated by MA Right-to-Know Law present.

US. Pennsylvania RTK - Hazardous Substances

No ingredient regulated by PA Right-to-Know Law present.

US. Rhode Island RTK

No ingredient regulated by RI Right-to-Know Law present.



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| |
|--|
| 16. Other information, including date of preparation or last revision |
|--|

Issue Date: 03/29/2019

Version #: 1.1

Revision Information:

Source of information: European Chemicals Agency (ECHA): Information on Chemicals.

Further Information: No data available.

Disclaimer: Disclaimer:
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SAFETY DATA SHEET

1. Identification

Product identifier

| Product No.: | Product name: | Common name(s), synonym(s) |
|--------------|------------------------------------|----------------------------|
| 660585 | BD™ Detergent Solution Concentrate | |

Other means of identification

SDS number: 088100200356

Recommended use and restriction on use

Recommended use: Scientific and Industrial laboratory use.

Restrictions on use: None known.

Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name: Becton, Dickinson and Company - BD Biosciences
Address: 2350 Qume Drive
95131 San Jose, CA USA
Telephone: 1 877 232 8995 or 1 800 424 9300
Fax:
Contact Person: Technical Services
E-mail: ResearchApplications@bd.com or ClinicalApplications@bd.com

Emergency telephone number: ChemTrec 1 800 424 9300

2. Hazard(s) identification

Hazard Classification

Health Hazards

| | |
|-----------------------------------|-------------|
| Skin Corrosion/Irritation | Category 1A |
| Serious Eye Damage/Eye Irritation | Category 1 |

Label Elements

Hazard Symbol:



Signal Word: Danger

Hazard Statement: H314: Causes severe skin burns and eye damage.



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Precautionary Statements

| | |
|---|--|
| Prevention: | P260: Do not breathe dust/fume/gas/mist/vapors/spray. P264: Wash thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. |
| Response: | P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P310: Immediately call a POISON CENTER/doctor. P321: Specific treatment (see on this label). P363: Wash contaminated clothing before reuse. |
| Storage: | P405: Store locked up. |
| Disposal: | P501: Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. |
| Other hazards which do not result in GHS classification: | None. |

3. Composition/information on ingredients

Mixtures

| Chemical Identity | Common name and synonyms | CAS number | Content in percent (%)* |
|-------------------------|--------------------------|------------|-------------------------|
| Acetic acid, 2-hydroxy- | | 79-14-1 | 10% |

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

| | |
|-----------------------------|---|
| General information: | Causes severe skin burns and eye damage. Get immediate medical advice/attention. |
| Ingestion: | Call a physician or poison control center immediately. Rinse mouth thoroughly. Do not induce vomiting. If vomiting occurs, the head should be kept low so that stomach vomit doesn't enter the lungs. |



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| | |
|----------------------|--|
| Inhalation: | Move to fresh air. Get medical attention if any discomfort continues. |
| Skin Contact: | Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Get medical attention promptly if symptoms occur after washing. |
| Eye contact: | Important! Immediately rinse with water for 60 minutes. Get medical attention immediately. Continue to rinse. |

Most important symptoms/effects, acute and delayed

| | |
|------------------|--|
| Symptoms: | Symptoms may be delayed. |
| Hazards: | Causes severe skin burns and eye damage. |

Indication of immediate medical attention and special treatment needed

| | |
|-------------------|--|
| Treatment: | IF exposed or concerned: Get medical advice/attention. |
|-------------------|--|

| |
|----------------------------------|
| 5. Fire-fighting measures |
|----------------------------------|

| | |
|------------------------------|---|
| General Fire Hazards: | Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate. Use water to keep fire exposed containers cool and disperse vapors. |
|------------------------------|---|

Suitable (and unsuitable) extinguishing media

| | |
|--|--|
| Suitable extinguishing media: | Use water fog, alcohol-resistant foam, dry chemical or carbon dioxide (CO ₂) to extinguish flames. |
| Unsuitable extinguishing media: | Do not use water jet as an extinguisher, as this will spread the fire. |

| | |
|--|--|
| Specific hazards arising from the chemical: | Fire or excessive heat may produce hazardous decomposition products. |
|--|--|

Special protective equipment and precautions for firefighters

| | |
|--|--|
| Special fire fighting procedures: | No unusual fire or explosion hazards noted. |
| Special protective equipment for fire-fighters: | Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA. |

| |
|---------------------------------------|
| 6. Accidental release measures |
|---------------------------------------|



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Personal precautions, protective equipment and emergency procedures:

Ensure suitable personal protection (including respiratory protection) during removal of spillages in a confined area. Ventilate closed spaces before entering them. Avoid breathing mists or vapors. Keep unauthorized personnel away.

Methods and material for containment and cleaning up:

Stop leak if possible without any risk. Prevent runoff from entering drains, sewers, or streams. Dike far ahead of larger spills for later disposal. Absorb in vermiculite, dry sand or earth and place into containers. See Section 8 of the SDS for Personal Protective Equipment. For waste disposal, see section 13 of the SDS.

Environmental Precautions:

Do not contaminate water sources or sewer.

7. Handling and storage

Precautions for safe handling:

Avoid contact with eyes and prolonged or repeated contact with skin. Avoid inhalation of vapors and spray mists. Observe good industrial hygiene practices. Wear appropriate personal protective equipment. Provide good ventilation.

Conditions for safe storage, including any incompatibilities:

Store in original tightly closed container. Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures.

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

None of the components have assigned exposure limits.

Appropriate Engineering Controls

Adequate ventilation should be provided so that exposure limits are not exceeded. Eye wash facilities and emergency shower must be available when handling this product.

Individual protection measures, such as personal protective equipment

General information:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing to remove contaminants. Discard contaminated footwear that cannot be cleaned.

Eye/face protection:

Wear safety glasses with side shields (or goggles) and a face shield.

Skin Protection

Hand Protection:

Suitable gloves can be recommended by the glove supplier.

Other:

Chemical resistant clothing

Respiratory Protection:

In case of inadequate ventilation use suitable respirator.



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Hygiene measures: Observe good industrial hygiene practices. Wash at the end of each work shift and before eating, smoking and using the toilet.

9. Physical and chemical properties

Appearance

Physical state: liquid
Form: No data available.
Color: Pale yellow

Odor: Odorless
Odor threshold: No data available.
pH: 2.5

Melting point/freezing point: No data available.

Initial boiling point and boiling range: No data available.

Flash Point: No data available.

Evaporation rate: No data available.

Flammability (solid, gas): No data available.

Upper/lower limit on flammability or explosive limits

Flammability limit - upper (%): No data available.

Flammability limit - lower (%): No data available.

Explosive limit - upper (%): No data available.

Explosive limit - lower (%): No data available.

Vapor pressure: No data available.

Vapor density: No data available.

Relative density: No data available.

Solubility(ies)

Solubility in water: Very Soluble

Solubility (other): No data available.

Partition coefficient (n-octanol/water): No data available.

Auto-ignition temperature: No data available.

Decomposition temperature: No data available.

Viscosity: No data available.

10. Stability and reactivity

Reactivity: Product is not reactive under normal conditions and recommended use.

Chemical Stability: No data available.

Possibility of hazardous reactions: Stable; however, may decompose if heated.

Conditions to avoid: Avoid exposure to high temperatures or direct sunlight. Do not freeze.



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| | |
|--|--|
| Incompatible Materials: | Avoid contact with oxidizers or reducing agents. |
| Hazardous Decomposition Products: | By heating and fire, corrosive vapors/gases may be formed. |

11. Toxicological information

Information on likely routes of exposure

| | |
|----------------------|--------------------|
| Ingestion: | No data available. |
| Inhalation: | No data available. |
| Skin Contact: | No data available. |
| Eye contact: | No data available. |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|----------------------|--------------------|
| Ingestion: | No data available. |
| Inhalation: | No data available. |
| Skin Contact: | No data available. |
| Eye contact: | No data available. |

Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

| | |
|-------------------|--------------------|
| Oral | |
| Product: | No data available. |
| Dermal | |
| Product: | No data available. |
| Inhalation | |
| Product: | No data available. |

| | |
|-------------------------------|--------------------|
| Repeated dose toxicity | |
| Product: | No data available. |

Specified substance(s):

| | |
|-------------------------|---|
| Acetic acid, 2-hydroxy- | LOAEL (Rat(Female, Male), Oral, 90 - 131 d): 300 mg/kg Oral Experimental result, Key study NOAEL (Rat(Male), Oral, 90 - 131 d): 150 mg/kg Oral Experimental result, Key study NOAEL (Rat(Male), Inhalation): 0.23 mg/l Inhalation Experimental result, Supporting study NOAEL (Rat(Female), Oral, 90 - 131 d): 600 mg/kg Oral Experimental result, |
|-------------------------|---|



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Key study
NOAEL (Rat(Female, Male), Oral, 90 - 131 d): 600 mg/kg Oral Experimental result, Key study

Skin Corrosion/Irritation

Product: No data available.

Specified substance(s):

Acetic acid, 2-hydroxy- in vivo (Rabbit): Corrosive Experimental result, Key study

Serious Eye Damage/Eye Irritation

Product: No data available.

Respiratory or Skin Sensitization

Product: No data available.

Specified substance(s):

Acetic acid, 2-hydroxy- Skin sensitization:, in vivo (Guinea pig): Non sensitising

Carcinogenicity

Product: No data available.

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:

No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:

No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):

No carcinogenic components identified

Germ Cell Mutagenicity

In vitro

Product: No data available.

In vivo

Product: No data available.

Reproductive toxicity

Product: No data available.

Specific Target Organ Toxicity - Single Exposure

Product: No data available.

Specific Target Organ Toxicity - Repeated Exposure

Product: No data available.



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Aspiration Hazard

Product: No data available.

Other effects: No data available.

12. Ecological information

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish

Product: Not expected to be harmful to aquatic organisms.

Aquatic Invertebrates

Product: No data available.

Specified substance(s):

Acetic acid, 2-hydroxy- EC 50 (Daphnia magna, 48 h): 141 mg/l Experimental result, Key study
EC 50 (Daphnia magna, 24 h): 141 mg/l Experimental result, Key study
NOAEL (Daphnia magna, 48 h): 100 mg/l Experimental result, Key study

Chronic hazards to the aquatic environment:

Fish

Product: No data available.

Aquatic Invertebrates

Product: No data available.

Toxicity to Aquatic Plants

Product: No data available.

Persistence and Degradability

Biodegradation

Product: No data available.

Specified substance(s):

Acetic acid, 2-hydroxy- 78 % (11 d) Detected in water. Experimental result, Key study
50 % (2 d) Sediment Experimental result, Supporting study
89.6 % (7 d) Detected in water. Experimental result, Supporting study
96 % (28 d) Sediment Experimental result, Supporting study
10 % (1 d) Sediment Experimental result, Supporting study

BOD/COD Ratio



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Product: No data available.

**Bioaccumulative potential
Bioconcentration Factor (BCF)**

Product: No data available.

Partition Coefficient n-octanol / water (log Kow)

Product: No data available.

Specified substance(s):

Acetic acid, 2-hydroxy- Log Kow: -1.11

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments

Acetic acid, 2-hydroxy- No data available.

Other adverse effects: No data available.

| |
|------------------------------------|
| 13. Disposal considerations |
|------------------------------------|

General information: Dispose of waste and residues in accordance with local authority requirements.

Disposal instructions: This material and/or its container must be disposed of as hazardous waste.

Contaminated Packaging: No data available.

| |
|----------------------------------|
| 14. Transport information |
|----------------------------------|

| | |
|--------------------------------------|----------------|
| DOTUN Number: | Not regulated. |
| UN Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es) | |
| Class: | Not regulated. |
| Label(s): | Not regulated. |
| Packing Group: | Not regulated. |
| Marine Pollutant: | Not regulated. |
| Limited quantity | Not regulated. |
| Excepted quantity | Not regulated. |
| Special precautions for user: | Not regulated. |



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IMDG

| | |
|-------------------------------|----------------|
| UN Number: | Not regulated. |
| UN Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es) | |
| Class: | Not regulated. |
| Subsidiary risk: | Not regulated. |
| EmS No.: | Not regulated. |
| Packing Group: | Not regulated. |
| Environmental Hazards | |
| Marine Pollutant: | Not regulated. |
| Special precautions for user: | Not regulated. |

IATA

| | |
|-------------------------------|----------------|
| UN Number: | Not regulated. |
| Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es): | |
| Class: | Not regulated. |
| Subsidiary risk: | Not regulated. |
| Packing Group: | Not regulated. |
| Environmental Hazards | |
| Marine pollutant: | Not regulated. |
| Special precautions for user: | Not regulated. |

15. Regulatory information

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

None present or none present in regulated quantities.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

None present or none present in regulated quantities.

CERCLA Hazardous Substance List (40 CFR 302.4):

None present or none present in regulated quantities.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate (Acute) Health Hazards
Skin Corrosion or Irritation
Serious eye damage or eye irritation

SARA 302 Extremely Hazardous Substance

None present or none present in regulated quantities.



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SARA 304 Emergency Release Notification

None present or none present in regulated quantities.

SARA 311/312 Hazardous Chemical

| <u>Chemical Identity</u> | <u>Threshold Planning Quantity</u> |
|--------------------------|------------------------------------|
| Acetic acid, 2-hydroxy- | 10000 lbs |

SARA 313 (TRI Reporting)

None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)

None present or none present in regulated quantities.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):

None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65

No ingredient requiring a warning under CA Prop 65.

US. New Jersey Worker and Community Right-to-Know Act

No ingredient regulated by NJ Right-to-Know Law present.

US. Massachusetts RTK - Substance List

No ingredient regulated by MA Right-to-Know Law present.

US. Pennsylvania RTK - Hazardous Substances

No ingredient regulated by PA Right-to-Know Law present.

US. Rhode Island RTK

No ingredient regulated by RI Right-to-Know Law present.

| |
|--|
| 16. Other information, including date of preparation or last revision |
|--|

Issue Date: 03/29/2019

Version #: 1.1

Revision Information:

Further Information: No data available.



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SAFETY DATA SHEET

1. Identification

Product identifier

| Product No.: | Product name: | Common name(s), synonym(s) |
|--------------|---------------------------------------|----------------------------|
| 660586 | BD™ Extended Flow Cell Clean Solution | |

Other means of identification

SDS number: 088100200357

Recommended use and restriction on use

Recommended use: Reserved for industrial and professional use.

Restrictions on use: None known.

Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name: Becton, Dickinson and Company - BD Biosciences
Address: 2350 Qume Drive
95131 San Jose, CA USA
Telephone: 1 877 232 8995 or 1 800 424 9300
Fax:
Contact Person: Technical Services
E-mail: ResearchApplications@bd.com or ClinicalApplications@bd.com

Emergency telephone number: ChemTrec 1 800 424 9300

2. Hazard(s) identification

Hazard Classification

Not classified

Label Elements

Hazard Symbol: No symbol
Signal Word: No signal word.
Hazard Statement: Not applicable
Precautionary Statements Not applicable

Other hazards which do not result in GHS classification: None.

3. Composition/information on ingredients



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Mixtures

| Chemical Identity | Common name and synonyms | CAS number | Content in percent (%)* |
|-------------------|--------------------------|------------|-------------------------|
| Ethanol | | 64-17-5 | 4.7184% |
| Methanol | | 67-56-1 | 0.2483% |

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

| | |
|-----------------------------|---|
| General information: | Get medical attention if symptoms occur. |
| Ingestion: | Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person. |
| Inhalation: | Provide fresh air, warmth and rest, preferably in comfortable upright sitting position. |
| Skin Contact: | Wash contact areas with soap and water. Remove contaminated clothing. Launder contaminated clothing before reuse. |
| Eye contact: | Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. |

Most important symptoms/effects, acute and delayed

Symptoms: No data available.

Indication of immediate medical attention and special treatment needed

Treatment: No data available.

5. Fire-fighting measures

General Fire Hazards: Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate. Use water spray to keep fire-exposed containers cool.

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media: Not applicable

Specific hazards arising from the chemical: Fire or excessive heat may produce hazardous decomposition products.



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Special protective equipment and precautions for firefighters

Special fire fighting procedures: No unusual fire or explosion hazards noted.

Special protective equipment for fire-fighters: Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: Contact local authorities in case of spillage to drain/aquatic environment. Ensure suitable personal protection (including respiratory protection) during removal of spillages in a confined area.

Methods and material for containment and cleaning up: Absorb spillage with suitable absorbent material. Prevent runoff from entering drains, sewers, or streams. See Section 8 of the SDS for Personal Protective Equipment. For waste disposal, see section 13 of the SDS.

Environmental Precautions: Avoid release to the environment.

7. Handling and storage

Precautions for safe handling: When using do not eat, drink or smoke. Read and follow manufacturer's recommendations. Use personal protective equipment as required.

Conditions for safe storage, including any incompatibilities: Store in a cool, dry place. Keep container tightly closed.

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

| Chemical Identity | Type | Exposure Limit Values | Source |
|-------------------|---------|-----------------------|---|
| Ethanol | TWA | 1,000 ppm 1,900 mg/m3 | US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989) |
| | TWA | 1,000 ppm 1,900 mg/m3 | US. Tennessee. OELs. Occupational Exposure Limits, Table Z1A (06 2008) |
| | AN ESL | 1,000 ppb | US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010) |
| | ST ESL | 10,000 ppb | US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010) |
| | AN ESL | 1,880 µg/m3 | US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010) |
| | ST ESL | 18,800 µg/m3 | US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010) |
| | TWA PEL | 1,000 ppm 1,900 mg/m3 | US. California Code of Regulations, Title 8, Section 5155. Airborne Contaminants (08 |



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| | | | |
|----------|---------|-----------------------|--|
| | | | 2010) |
| | STEL | 1,000 ppm | US. ACGIH Threshold Limit Values (12 2010) |
| | REL | 1,000 ppm 1,900 mg/m3 | US. NIOSH: Pocket Guide to Chemical Hazards (2005) |
| | PEL | 1,000 ppm 1,900 mg/m3 | US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006) |
| Methanol | STEL | 250 ppm 325 mg/m3 | US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989) |
| | TWA | 200 ppm 260 mg/m3 | US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989) |
| | STEL | 250 ppm 325 mg/m3 | US. Tennessee. OELs. Occupational Exposure Limits, Table Z1A (06 2008) |
| | TWA | 200 ppm 260 mg/m3 | US. Tennessee. OELs. Occupational Exposure Limits, Table Z1A (06 2008) |
| | ST ESL | 2,620 µg/m3 | US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010) |
| | AN ESL | 200 ppb | US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010) |
| | AN ESL | 262 µg/m3 | US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010) |
| | ST ESL | 2,000 ppb | US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010) |
| | STEL | 250 ppm 325 mg/m3 | US. California Code of Regulations, Title 8, Section 5155. Airborne Contaminants (08 2010) |
| | TWA PEL | 200 ppm 260 mg/m3 | US. California Code of Regulations, Title 8, Section 5155. Airborne Contaminants (08 2010) |
| | Ceiling | 1,000 ppm | US. California Code of Regulations, Title 8, Section 5155. Airborne Contaminants (08 2010) |
| | STEL | 250 ppm | US. ACGIH Threshold Limit Values (12 2010) |
| | TWA | 200 ppm | US. ACGIH Threshold Limit Values (12 2010) |
| | REL | 200 ppm 260 mg/m3 | US. NIOSH: Pocket Guide to Chemical Hazards (2005) |
| | STEL | 250 ppm 325 mg/m3 | US. NIOSH: Pocket Guide to Chemical Hazards (2005) |
| | PEL | 200 ppm 260 mg/m3 | US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006) |

Biological Limit Values

| Chemical Identity | Exposure Limit Values | Source |
|--|-----------------------|---------------------|
| Methanol (methanol: Sampling time: End of shift.) | 15 mg/l (Urine) | ACGIH BEI (03 2013) |

Appropriate Engineering Controls

No special requirements under ordinary conditions of use and with adequate ventilation.



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Individual protection measures, such as personal protective equipment

| | |
|--------------------------------|---|
| General information: | Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing to remove contaminants. Discard contaminated footwear that cannot be cleaned. |
| Eye/face protection: | Wear safety glasses with side shields (or goggles). |
| Skin Protection | |
| Hand Protection: | Chemical resistant gloves Suitable gloves can be recommended by the glove supplier. Wash hands after contact. |
| Other: | Wear a lab coat or similar protective clothing. |
| Respiratory Protection: | If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. |
| Hygiene measures: | Observe good industrial hygiene practices. |

9. Physical and chemical properties

Appearance

| | |
|--|--------------------|
| Physical state: | liquid |
| Form: | Aqueous Solution |
| Color: | Colorless |
| Odor: | Characteristic |
| Odor threshold: | No data available. |
| pH: | No data available. |
| Melting point/freezing point: | No data available. |
| Initial boiling point and boiling range: | No data available. |
| Flash Point: | No data available. |
| Evaporation rate: | No data available. |
| Flammability (solid, gas): | No data available. |
| Upper/lower limit on flammability or explosive limits | |
| Flammability limit - upper (%): | No data available. |
| Flammability limit - lower (%): | No data available. |
| Explosive limit - upper (%): | No data available. |
| Explosive limit - lower (%): | No data available. |
| Vapor pressure: | No data available. |
| Vapor density: | No data available. |
| Relative density: | No data available. |
| Solubility(ies) | |
| Solubility in water: | No data available. |



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| | |
|---|--------------------|
| Solubility (other): | No data available. |
| Partition coefficient (n-octanol/water): | No data available. |
| Auto-ignition temperature: | No data available. |
| Decomposition temperature: | No data available. |
| Viscosity: | No data available. |

10. Stability and reactivity

| | |
|--|---|
| Reactivity: | Stable under normal temperature conditions and recommended use. |
| Chemical Stability: | Material is stable under normal conditions. |
| Possibility of hazardous reactions: | Not determined. |
| Conditions to avoid: | Avoid exposure to high temperatures or direct sunlight. |
| Incompatible Materials: | Metals. Water reactive material. |
| Hazardous Decomposition Products: | Stable; however, may decompose if heated. |

11. Toxicological information

General information: No data on possible toxicity effects have been found.

Information on likely routes of exposure

| | |
|----------------------|---|
| Ingestion: | No harmful effects expected in amounts likely to be ingested by accident. |
| Inhalation: | Limited inhalation hazard at normal work temperatures. |
| Skin Contact: | Negligible irritation to skin at ambient temperatures. |
| Eye contact: | Elevated temperatures or mechanical action may form vapors, mist, or fumes which may be irritating to the eyes, nose, throat, or lungs. |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|----------------------|--------------------|
| Ingestion: | No data available. |
| Inhalation: | No data available. |
| Skin Contact: | No data available. |
| Eye contact: | No data available. |



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Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral

Product: ATEmix: 40,273.86 mg/kg

Dermal

Product: ATEmix: 120,821.59 mg/kg

Inhalation

Product: ATEmix: 1,208.22 mg/l

Repeated dose toxicity

Product: No data available.

Specified substance(s):

Ethanol

Based on available data, the classification criteria are not met.
LOAEL (Rat(Female, Male), Inhalation, 7,318 - 7,496 h): 1.3 mg/l Inhalation Read-across from supporting substance (structural analogue or surrogate), Weight of Evidence study
NOAEL (Guinea pig, Inhalation, 10.5 Weeks): 3,000 ppm(m) Inhalation Experimental result, Supporting study
LOAEL (Rat(Male), Inhalation, 1 - 6 Weeks): 13.3 mg/l Inhalation Read-across from supporting substance (structural analogue or surrogate), Supporting study
LOAEL (Monkey, Inhalation, 5 - 20 d): 3.99 mg/l Inhalation Read-across from supporting substance (structural analogue or surrogate), Supporting study

Methanol

NOAEL (Rat(Female, Male), Inhalation): 6.66 mg/l Inhalation Experimental result, Weight of Evidence study
LOAEL (Rat(Male), Inhalation, 1 - 6 Weeks): 13.3 mg/l Inhalation Experimental result, Supporting study
NOAEL (Rat(Male), Inhalation, 1 - 6 Weeks): 2.65 mg/l Inhalation Experimental result, Supporting study
NOAEL (Rat(Male), Inhalation, 1 - 6 Weeks): 0.26 mg/l Inhalation Experimental result, Supporting study
NOAEL (Rat(Female, Male), Inhalation, 7,318 - 7,496 h): 0.13 mg/l Inhalation Experimental result, Weight of Evidence study

Skin Corrosion/Irritation

Product: No data available.

Specified substance(s):

Ethanol

in vivo (Rabbit): Not irritant Experimental result, Key study



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Methanol in vivo (Rabbit): Not irritant Experimental result, Key study

Serious Eye Damage/Eye Irritation

Product: No data available.

Specified substance(s):

Ethanol in vivo (Rabbit, 24 - 72 hrs): Not irritating EU

Methanol in vivo (Rabbit, 24 - 72 hrs): Not irritating

Respiratory or Skin Sensitization

Product: No data available.

Specified substance(s):

Ethanol Based on available data, the classification criteria are not met.
Skin sensitization:, in vivo (Guinea pig): Non sensitising

Methanol Skin sensitization:, in vivo (Guinea pig): Non sensitising

Carcinogenicity

Product: No data available.

Specified substance(s):

Ethanol Based on available data, the classification criteria are not met.

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:

No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:

No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):

No carcinogenic components identified

Germ Cell Mutagenicity

In vitro

Product: No data available.

Specified substance(s):

Ethanol Based on available data, the classification criteria are not met.

In vivo

Product: No data available.

Specified substance(s):

Ethanol Based on available data, the classification criteria are not met.

Reproductive toxicity

Product: No data available.



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Specified substance(s):

Ethanol Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity - Single Exposure

Product: No data available.

Specified substance(s):

Ethanol Based on available data, the classification criteria are not met.

Methanol Oral: Nervous System - Causes damage to organs.

Specific Target Organ Toxicity - Repeated Exposure

Product: No data available.

Specified substance(s):

Ethanol Based on available data, the classification criteria are not met.

Aspiration Hazard

Product: No data available.

Other effects: No data available.

| |
|-----------------------------------|
| 12. Ecological information |
|-----------------------------------|

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish

Product: No negative effects on the aquatic environment are known.

Aquatic Invertebrates

Product: No negative effects on the aquatic environment are known.

Chronic hazards to the aquatic environment:

Fish

Product: No negative effects on the aquatic environment are known.

Aquatic Invertebrates

Product: No negative effects on the aquatic environment are known.

Toxicity to Aquatic Plants

Product: No negative effects on the aquatic environment are known.

Persistence and Degradability

Biodegradation

Product: Expected to be readily biodegradable.

BOD/COD Ratio

Product: No data available.



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Bioaccumulative potential

Bioconcentration Factor (BCF)

Product: No data available.

Specified substance(s):

| | |
|----------|--|
| Ethanol | Potential to bioaccumulate is low. Cyprinus carpio, Bioconcentration Factor (BCF): 4.5 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Supporting study Cyprinus carpio, Bioconcentration Factor (BCF): 3 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Supporting study Leuciscus idus, Bioconcentration Factor (BCF): 0.2 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Not specified Cyprinus carpio, Bioconcentration Factor (BCF): 1 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Supporting study |
| Methanol | Leuciscus idus, Bioconcentration Factor (BCF): < 10 Aquatic sediment Experimental result, Supporting study Cyprinus carpio, Bioconcentration Factor (BCF): 4.5 Aquatic sediment Experimental result, Supporting study Cyprinus carpio, Bioconcentration Factor (BCF): 1 Aquatic sediment Experimental result, Supporting study Cyprinus carpio, Bioconcentration Factor (BCF): 3 Aquatic sediment Experimental result, Supporting study Green algae (Chlorella fusca vacuolata), Bioconcentration Factor (BCF): 28,400 (Static) |

Partition Coefficient n-octanol / water (log Kow)

Product: No data available.

Specified substance(s):

| | |
|----------|----------------|
| Ethanol | Log Kow: -0.31 |
| Methanol | Log Kow: -0.77 |

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments

| | |
|----------|---------------------------|
| Ethanol | soil - Very mobile liquid |
| Methanol | No data available. |

Other adverse effects: The product is not expected to be hazardous to the environment.



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13. Disposal considerations

| | |
|--------------------------------|---|
| General information: | Dispose of waste and residues in accordance with local authority requirements. |
| Disposal instructions: | Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. |
| Contaminated Packaging: | No data available. |

14. Transport information

| | |
|--------------------------------------|----------------|
| DOTUN Number: | Not regulated. |
| UN Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es) | |
| Class: | Not regulated. |
| Label(s): | Not regulated. |
| Packing Group: | Not regulated. |
| Marine Pollutant: | Not regulated. |
| Limited quantity | Not regulated. |
| Excepted quantity | Not regulated. |
| Special precautions for user: | Not regulated. |

IMDG

| | |
|--------------------------------------|----------------|
| UN Number: | Not regulated. |
| UN Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es) | |
| Class: | Not regulated. |
| Subsidiary risk: | Not regulated. |
| EmS No.: | Not regulated. |
| Packing Group: | Not regulated. |
| Environmental Hazards | |
| Marine Pollutant: | Not regulated. |
| Special precautions for user: | Not regulated. |



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IATA

| | |
|-------------------------------|----------------|
| UN Number: | Not regulated. |
| Proper Shipping Name: | Not regulated. |
| Transport Hazard Class(es): | |
| Class: | Not regulated. |
| Subsidiary risk: | Not regulated. |
| Packing Group: | Not regulated. |
| Environmental Hazards | |
| Marine pollutant: | Not regulated. |
| Special precautions for user: | Not regulated. |

15. Regulatory information

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

None present or none present in regulated quantities.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

None present or none present in regulated quantities.

CERCLA Hazardous Substance List (40 CFR 302.4):

| <u>Chemical Identity</u> | <u>Reportable quantity</u> |
|--------------------------|----------------------------|
| Ethanol | 100 lbs. |
| Methanol | 5000 lbs. |

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Not classified
Not classified

SARA 302 Extremely Hazardous Substance

None present or none present in regulated quantities.

SARA 304 Emergency Release Notification

| <u>Chemical Identity</u> | <u>Reportable quantity</u> |
|--------------------------|----------------------------|
| Ethanol | 100 lbs. |
| Methanol | 5000 lbs. |

SARA 311/312 Hazardous Chemical

| <u>Chemical Identity</u> | <u>Threshold Planning Quantity</u> |
|--------------------------|------------------------------------|
| Ethanol | 10000 lbs |
| Methanol | 10000 lbs |

SARA 313 (TRI Reporting)

None present or none present in regulated quantities.



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Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)

None present or none present in regulated quantities.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):

None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65

WARNING: This product can expose you to chemicals including, Ethanol, which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm.
This product can expose you to chemicals including, Methanol, which is [are] known to the State of California to cause birth defects or other reproductive harm.
For more information go to www.P65Warnings.ca.gov.

US. New Jersey Worker and Community Right-to-Know Act

Chemical Identity

Ethanol

US. Massachusetts RTK - Substance List

Chemical Identity

Ethanol

US. Pennsylvania RTK - Hazardous Substances

Chemical Identity

Ethanol

US. Rhode Island RTK

Chemical Identity

Ethanol

| |
|--|
| 16. Other information, including date of preparation or last revision |
|--|

Issue Date: 03/29/2019

Version #: 1.1

Revision Information:

Source of information: European Chemicals Agency (ECHA): Information on Chemicals.

Further Information: No data available.



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