

Manufacturer: Becton, Dickinson and Company

BD Biosciences 2350 Qume Drive

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Conformity Annex III of the IVD Directive 98/79/EC. assessment procedure:

Product: 340167 - BD FACSCount (TM) Reagent Kit

We hereby declare that the above mentioned product(s) manufactured after 2017/10/01 complies with the above listed Directive(s) and its relevant transposition into national laws of the member states into which we place the devices.

Signed In San Jose:	2017/10/01
Name and Authority:	Paul Arrendell, WW VP Quality Management
Signature:	Paul amendell

Technical File Number:



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Conformity assessment procedure:

Annex III of the IVD Directive 98/79/EC.

Product: 340166 - BD FACSCount (TM) Control Kit

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Signed In San Jose:	2017/10/01
Name and Authority:	Paul Arrendell, WW VP Quality Management
Signature:	Paul amendell

Technical File Number:

BD FACSCount™ System





An easy-to-use and complete system for cost-effective monitoring of HIV/AIDS



A Robust and Trusted System for Determining Absolute Cell Counts and CD4 Percentages

The BD FACSCount™ system is a proven, turnkey system designed to provide absolute and percentage results of CD4 T lymphocytes to stage progression of HIV/AIDS, to guide treatment decisions for HIV-infected persons, and to evaluate effectiveness of therapy in a wide range of laboratory settings.

As the system of choice for CD4 monitoring in global HIV/AIDS treatment programs for over a decade, the BD FACSCount system is recognized for its simplicity of operation, robust performance, and reliable results. Today clinicians in programs throughout Africa, Asia, Eastern Europe, and Latin America continue to rely on the system for cost-effective, simple, and dependable CD4 testing.

Recent improvement in the accessibility of drug therapies for HIV/AIDS and the accompanying requirement for effective monitoring of these therapies have kept BD focused on making CD4 testing technology as affordable, appropriate, and accessible as possible.

Since the first BD FACSCount system was delivered in 1994, BD has continued to be committed to technology innovation and investments that help people with immunodeficiency diseases as part of our larger global health initiatives and ongoing mission to help all people live healthy lives.

STREAMLINED

Proven Reliability and Ease-of-Use

Easy to Install, Set Up, and Run with Confidence

To provide users with reliable results independent of user training and lab infrastructure availability, the BD FACSCount system is designed for simplicity of installation, setup, and operation. The BD FACSCount system includes the BD FACSCount instrument, software, a workstation, reagents, and controls. The instrument is easy to install, operates from a standard electrical outlet, and requires no hardware adjustments or calibration. Only minimal training is needed to set up the instrument and to run samples.

Simple prompts on the display guide operators through testing, from input of patient information to final results. Results are objective, requiring no interpretation or subjective analysis by the operators.

Simple Three-Step Sample Preparation

Sample preparation follows an easy three-step process. First, blood is added to a tube that contains premeasured reagents. Then the sample is vortexed and incubated. In the second step, a fixative is added to the tube, which is then vortexed and incubated. In step three, the sample is vortexed and run on the instrument.

Simplified Sample Handling Sample preparation is an easy three-step process:



Step 1: Add 50 µL of blood to the reagent tube (containing premeasured reagents), vortex, and incubate.

WORKFLOW





Step 2: Add 50 μL of fixative solution to the sample tube, vortex, and incubate.



Step 3: Vortex and run on the BD FACSCount system.

Absolute Counts and Percentages

BD FACSCount CD4 Reagents

The BD FACSCount system precisely measures absolute numbers and percentage results of CD4-positive T lymphocytes, the cellular parameter most closely associated with HIV/AIDS disease progression and therapy decisions. The system also measures absolute numbers of CD3 and CD8 T lymphocytes. The system provides reproducible and accurate results even with low CD4 counts.

BD FACSCount reagents are provided as complete kits that streamline CD4 counting. These kits contain ready-to-use tubes with premeasured antibodies and beads for absolute counting, and fixative solution.

Three reliable assay kits are available to meet specific needs for CD4 counting. All BD FACSCount kits can be used with unlysed whole blood, which simplifies sample preparation and allows streamlining of the workflow.

BD FACSCount CD4 Reagent Kit

The BD FACSCount CD4 reagent kit enables the simultaneous enumeration of absolute counts and determination of CD4 percentages in unlysed whole blood. It is an essential tool in pediatric CD4 testing.*

BD FACSCount CD4/CD3 Reagent Kit

The BD FACSCount CD4/CD3 reagent kit allow the uncoupling of CD4 and CD3 enumerations from CD8. The single-tube format reduces cost and sample processing time, allowing limited resources to go further in the HIV/AIDS treatment program.

BD FACSCount Reagent Kit

The BD FACSCount Reagent kit is provided in a 2-tube format—one tube containing CD4 and CD3 antibodies and a second tube containing CD8 and CD3 antibodies—this assay delivers absolute CD4, CD3, and CD8 counts, and a CD4/8 ratio.

BD FACSCount CD4 Reagents



BD FACSCount CD4 Reagent (Cat. No. 339010)

This reagent delivers absolute CD4 counts and CD4 percentages.



BD FACSCount CD4/CD3 Reagent Kit (Cat. No. 342512)

This reagent delivers absolute CD4 counts.

^{*} Pattanapanyasat K, Sukapirom K, Kowawisatsut L, Thepthai C. New BD FACSCount™ CD4 reagent system for simultaneous enumeration of percent and absolute CD4 T-lymphocytes in HIV-1-infected pediatric patients. Clin Cytom. 2008;74 Suppl 1:S98-S106.

CONSISTENT RESULTS



BD Good Laboratory Practices Workshops

The BD commitment to help prevent, diagnose, and treat HIV/AIDs goes beyond the application of technology. BD actively collaborates across public and private sectors with national governments, non-governmental organizations, industry, faith-based organizations, public officials, and healthcare providers to create effective and sustainable programs to build healthcare capacity.

BD Good Laboratory Practices Workshops provide handson training to laboratory workers, focusing on the implementation of Standard Operating Procedures (SOPs) for immune system monitoring of HIV/AIDS patients (CD4 testing). The workshops also include training of fundamental laboratory practices such as quality control and blood sampling.

Thousands of healthcare workers in more than 50 developing countries have participated in the BD workshops, resulting in a significant improvement of clinical and laboratory services.



BD FACSCount Reagent Kit (Cat. No. 340167)

This reagent delivers absolute CD4, CD3, and CD8 counts, and a CD4/8 ratio

Easy-to-Use, Turnkey

A System of Choice for Quality

The BD FACSCount system has been an integral part of CD4 monitoring in global HIV/AIDS treatment programs for over a decade. On a worldwide level, the system's proven accuracy and quality have made it the preferred system for patient management.

System Performance, Linearity, and Accuracy

BD FACSCount control kits consist of paired control bead sets, containing beads at four levels: zero, low, medium, and high. BD FACSCount control beads can be added to samples prepared with normal blood to validate laboratory practices and methodology and system linearity. The control run generates a printed report summarizing system performance. The result of the last control run is reported on each subsequent sample printout, to to provide confidence in the result.

BD FACSCount Software

BD FACSCount software enables automated analysis without any operator intervention. The automatic identification of the beads and of the lymphocyte populations of interest, and calculation of the absolute counts (cells/µL) and percentages, allow a time- and costeffective workflow and minimizes potential errors.

Patients' results are summarized on a printed sample report that does not require interpretation or subjective analysis. Quality controls in the software ensure that reported results are accurate by detecting and flagging error conditions and suppressing results when control limits are exceeded.

BD FACSCount %CD4 Run Report

BD FACSCount Control Kit (Cat. No. 340166)

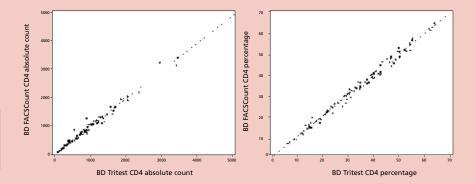




Accuracy and Precision of BD FACSCount CD4 Reagents

CD4 absolute count and percentage results were compared with results from BD Tritest™ CD3 FITC/CD4 PE/CD45 PerCP with BD Trucount™ tubes on the BD FACSCalibur flow cytometer using BD Multiset™ software.

Parameters	n	R ²	Slope	Intercept	Range
Absolute CD4 (cells/µL)	101	0.981	0.971	12.695	59 – 3,404
CD4 Percentage	99	0.99	0.999	-0.391	5.51 – 64.69



SERVICES

Committed to Customer Success

BD Biosciences is fully committed to the success and satisfaction of its customers. The BD FACSCount system is backed by a world-class service and support organization with unmatched flow cytometry experience. Since 1974, BD has been an innovation leader in cell analysis for optimal performance, ease of use, and improved workflow. This expertise is made available to BD customers through comprehensive training, applications and technical support, and expert field service.

BD people are never far away to help support you and your lab. You'll get answers from a single, local point of contact who is never more than two days away. BD has a proven track record of dependability and supply chain excellence that customers have come to rely on for consistent, timely delivery of reagents and supplies.

Training

Hands-on training provides participants with the skills and competency to perform reliable CD4 T lymphocyte enumeration using the BD FACSCount system. In addition, BD is working in developing countries to improve the fundamental capacity to deliver healthcare, including trained healthcare workers and access to clinical and laboratory products and services. With many years of experience both in clinical and in research studies, BD Biosciences scientific experts provide training on the use of BD flow cytometers and related BD applications. Trainings are offered at customer sites or in completely equipped BD Biosciences training centers.

Field service and support

When instrument installation or service is required, BD Biosciences provides a full range of support options from telephone troubleshooting to on-site visits. On-site service and maintenance agreements are available for long-term support.









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For In Vitro Diagnostic Use.

BD FACSCount CD4/CD3 reagents and BD FACSCount CD4/CD3 software are neither cleared for In Vitro Diagnostic Use nor CE marked under the IVD directive and are For Export Only. Not for sale or distribution in a number of jurisdictions, including US, Canada, Japan, and European Union Member States.

Purchase does not include or carry any right to resell or transfer this product either as a stand-alone product or as a component of another product. Any use of this product other than the permitted use without the express written authorization of Becton, Dickinson and Company is strictly prohibited. Product availability and prices are subject to change without notice.

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BD Biosciences 2350 Qume Drive San Jose, CA 95131 bdbiosciences.com



BD FACSCount System Quick Reference

A Complete System for Measuring Absolute CD4 Counts and Percentages in HIV/AIDS Patients



For Use with BD FACSCount™ CD4 Reagents, BD FACSCount Controls, and BD FACSCount CD4 Software Use this after you are familiar with the procedures in the appropriate BD FACSCount system user's guide and package insert.

1 Starting Up

- 1. Make sure that the software protocol disk for BD FACSCount CD4 reagents is in the drive.
- 2. Turn on the power to the instrument.
- 3. Fill the system fluid reservoir with BD FACSFlow™ sheath fluid.
- 4. Empty the waste reservoir.
- CAUTION: Do not dispose of waste reservoir contents until at least 30 minutes after the completion of the last run. This helps inactivate biohazardous materials before disposal.
- 5. Add 200 mL of BD™ FACSClean solution or undiluted bleach to the
- 6. Check for air in the flow cell and prime the system, if necessary

3 Running Controls

- 1. Press [Control] on the BD FACSCount screen.
- 2. Enter the eight-digit control bead lot code.



3. Enter the bead counts for the Low, Medium, and High controls and press [Confirm].

4. Enter the eight-digit reagent lot code.



- 5. Enter the CD4 reference bead count for the reagent lot and press [Confirm].
- 6. Enter the normal control ID and press [Enter].
- 7. Vortex the CD4-Low reagent tube upright for 6 seconds. Set the vortex speed to a setting that causes the liquid to rise to the top of the reagent tube.
- 8. Uncap the CD4-Low tube, place it in the sample holder, and press [Run].
- 9. Remove the CD4-Low tube and recap it.
- 10. Follow steps 7 through 9 for the both the CD4-Medium and CD4-High reagent tubes.

2 Preparing Controls and Samples

Collect blood in BD Vacutainer® EDTA tubes or equivalent. Prepare controls and patient samples by adding blood, then fixative solution to the reagent tubes. Before running controls, add control beads.

Preparing Tubes

1. For controls, label the tabs of three reagent tubes: Low, Medium, and



2. For each patient specimen, label the tab of a reagent tube with the patient ID or accession number.



- 3. Vortex each reagent tube upside down for 6 seconds, then upright
- 4. Open the reagent tubes with the coring station.



Adding Blood to Controls

- 1. Invert the normal whole blood BD Vacutainer EDTA tube 5 to 10 times to adequately mix.
- 2. Reverse pipette 50 µL of normal whole blood into each reagent tube labeled Low, Medium, and High. Change tips between tubes.



3. Cap the tubes and vortex upright for 6 seconds.

Adding Blood to Samples

- 1. Invert the patient specimen BD Vacutainer EDTA tube 5 to 10 times to adequately mix.
- 2. Reverse pipette 50 μ L of specimen whole blood into the reagent tube labeled with the corresponding identification number.
- 3. Cap the tube and vortex upright for 6 seconds.
- 4. Repeat steps 1 through 3 to prepare a sample tube for each patient specimen. Change tips between tubes.

Incubating Tubes

Incubate controls and samples in the dark for 30 minutes at room

NOTE: Incubation should not exceed 40 minutes.

Adding Fixative

- 1. Uncap the tubes and reverse pipette 50 µL of fixative solution into each tube. Change tips between tubes.
- 2. Recap the tubes and vortex upright for 6 seconds.

NOTE: Stained controls can be stored up to 24 hours before adding control beads. Run samples on the BD FACSCount instrument within 48 hours of preparation.

Adding Control Beads

1. Place the Zero/Low and Medium/High control beads in the control area of the workstation. See the user's guide if you are opening control beads for the first time.



- 2. Uncap the tubes labeled Zero, Low, Medium, and High.
- 3. Vortex the Zero/Low control bead pair for 6 seconds and reverse pipette 50 µL of Low control beads into the tube labeled Low. Change tips between tubes.
- 4. Vortex the Medium/High control bead pair for 6 seconds and reverse pipette 50 µL of the Medium control beads into the tube labeled Medium. Change tips between tubes.
- 5. Reverse pipette 50 µL of the High control beads into the tube labeled High.
- NOTE: Run controls on the BD FACSCount instrument within 2 hours

of adding the control beads.

6. Recap the tubes.

4 Running Samples

- 1. Press [Sample] on the BD FACSCount screen.
- 2. Enter or verify the reagent lot code and reference bead count and press [Confirm].
- 3. Enter the patient ID or accession number on the Sample screen.
- 4. Vortex the reagent tube upright for 6 seconds. Set the vortex speed to a setting that causes the liquid to rise to the top of the reagent tube.
- 5. Uncap the CD4 tube, place it in the sample holder, and press [Run].
- 6. Remove the CD4 tube and recap it.
- 7. Repeat steps 3 through 6 for each remaining sample. NOTICE: Perform instrument daily cleaning and shutdown after running controls or samples.

5 Daily Cleaning

Instrument

- 1. Press [Utility] on the BD FACSCount screen.
- 2. Press [Clean], and then press [Daily]
- Place a tube of BD FACSClean solution or a 1:3 dilution of bleach in the sample holder and press [Run].
- 4. Place a tube of BD™ FACSRinse solution or distilled water in the sample holder and press [Run].

Workstation

Wipe down the workstation with a soft cloth dipped in a 1:10 dilution

Coring Station

- 1. Invert the coring station over a sink and allow warm water to run into the metal openings surrounding the cutters.
- 2. Dry the coring station with a clean, dry cloth.

Electronic Pipette

Wipe down the pipette with a soft cloth dipped in a mild detergent solution.

Shutdown

NOTICE: Perform daily cleaning before you turn the instrument off at the end of each day.

- 1. Press [Utility] on the BD FACSCount screen.
- 2. Press [Shutdown].
- 3. Place a tube of BD FACSRinse solution or distilled water in the sample holder and press [Run].
- 4. Leave the instrument power on to continue running samples later in the day, or turn off the instrument power to complete the shutdown.

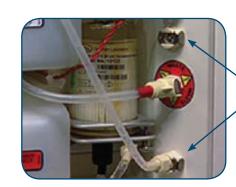
CAUTION: Bypass the saline filter to prevent damage from cleaning

6 Maintenance

Long Cleaning

Perform the following steps to clean the fluidics once a month or every 500 samples, whichever occurs first. Additionally, perform the long clean procedure when instructed to in Troubleshooting, or when recommended by your BD service representative.

- 1. Remove the sheath tank and discard the solution.
- 2. Rinse the tank, and fill it with 2 liters of BD FACSClean solution or a 1:10 bleach solution.
- 3. Place the sheath tank back on the instrument, bypassing the sheath filter.



sheath filter bypassed

and rinsing solutions.

4. Empty the waste tank and reconnect.

6. Press [Clean], and then press [Long].

5. Press [Utility] on the BD FACSCount screen.

7. Press [Confirm] that the sheath filter is bypassed.

9. Replace the cleaning solution in the sheath tank with BD FACSRinse solution or distilled water, and press [Confirm]. 10. Place a tube of BD FACSRinse solution or distilled water in the sample

8. Place a tube of BD FACSClean solution or a 1:3 dilution of bleach in

the sample holder and press [Confirm], and then [Run].

- holder and press [Run]. 11. Empty the sheath tank and fill it with BD FACSFlow sheath fluid.
- 12. Connect the sheath tank and reconnect the saline filter connector to
- 13. Perform the shutdown procedure (see *Daily Cleaning* above).

• Disconnect the sheath filter output tubing connector and set it aside.

• Connect the sheath tank output tubing connector to where the sheath filter output tubing connector was connected.

Local BD Biosciences Office Address BD Biosciences Sales Representative BD Biosciences Service Representative Contact Information

For more information, visit **bdbiosciences.com** or contact your local BD Biosciences representative.



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Conformity assessment procedure:

Annex III of the IVD Directive 98/79/EC.

Product: 345768 - CD4 (SK3) FITC 345771 - CD4 (SK3) APC

341115 - CD4 (SK3) APC-Cy (TM) 7

345770 - CD4 (SK3) PerCP

332772 - CD4 (SK3) PerCP-Cy (TM) 5.5

345769 - CD4 (SK3) PE

348809 - CD4 (SK3) PE-Cy (TM) 7

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Signed In San Jose: 2017/10/01

Name and Authority: Paul Arrendell, WW VP Quality Management

Signature: Paul Arrendell

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Conformity assessment procedure:

Annex III of the IVD Directive 98/79/EC.

Product: 340914 - BD (TM) Multi-Check CD4 Low Control

340916 - BD (TM) Multi-Check CD4 Low Control 340915 - BD (TM) Multi-Check CD4 Low Control

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Name and Authority:	Paul Arrendell, WW VP Quality Management
Signature:	Paul amendell

Technical File Number:



Last revised date: 05/06/2020

Becton, Dickinson and Company BD, Franklin Lakes, NJ 07417 USA www.bd.com

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 Category 2

environment

Chronic hazards to the aquatic Category 3

environment

Label Elements

Hazard Symbol:

SDS US 1/12





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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

SDS US 2/12



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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.

SDS US 3/12



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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	Туре	Exposure Limit Values	Source
Sodium hydroxide (Na(OH))	Ceiling	2 mg/m3 US. OSHA Table Z-1-A (29 CFR 1910.1000), as amended (1989)	
	Ceiling	2 mg/m3	US. Tennessee. OELs. Occupational Exposure Limits, Table Z1A, as amended (06 2008)
Sodium hydroxide (Na(OH)) - Particulate.	AN ESL	2 μg/m3	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality), as amended (07 2011)
	ST ESL	20 μg/m3	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality), as amended (07 2011)
Sodium hydroxide (Na(OH))	Ceiling	2 mg/m3	US. California Code of Regulations, Title 8, Section 5155. Airborne Contaminants, as amended (08 2010)
	Ceiling	2 mg/m3	US. ACGIH Threshold Limit Values, as amended (12 2010)
	Ceil_Time	2 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards, as amended (2005)
	PEL	2 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000), as amended (02 2006)
	IDLH	10 mg/m3	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.

SDS US 4/12



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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. No data available. :Ha Melting point/freezing point: No data available. Initial boiling point and boiling range: No data available. No data available. Flash Point: **Evaporation rate:** No data available. Flammability (solid, gas): No data available.

Upper/lower limit on flammability or explosive limits

Flammability limit - upper (%):

Flammability limit - lower (%):

Explosive limit - upper (%):

Explosive limit - lower (%):

Vapor pressure:

Vapor density:

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):

Auto-ignition temperature:

No data available.

No data available.

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

sodium salt (1:1)

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.

Tro data available

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments

Hypochlorous acid, sodium

No data available.

salt (1:1)

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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BD

Last revised date: 05/06/2020

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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.

100 lbs.

CERCLA Hazardous Substance List (40 CFR 302.4):

<u>Chemical Identity</u> <u>Reportable quantity</u>

Hypochlorous acid,

sodium salt (1:1)
Sodium hydroxide 1000 lbs.

(Na(OH))

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, Reportable quantity: 100 lbs.

sodium salt (1:1)

Sodium hydroxide Reportable quantity: 1000 lbs.

(Na(OH))

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

Chemical Identity

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.

Disclaimer: Disclaimer:

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SAFETY DATA SHEET

1. Identification

Product identifier

Product name: BD FACSFlow™ Sheath Fluid Product No.: 342003

Other means of identification

SDS number: 088100019518

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, CAUSA

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 not applicable

Statements

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	0.064%

^{*} 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

Store in a cool, dry place. Keep container tightly closed.

incompatibilities:

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

Chemical Identity	Туре	Exposure Limit Values	Source
Sodium fluoride (NaF) - as F	TWA	2.5 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
	TWA	2.5 mg/m3	US. ACGIH Threshold Limit Values (12 2010)
	REL	2.5 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
	PEL	2.5 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Sodium fluoride (NaF) - Dust.	TWA	2.5 mg/m3	US. OSHA Table Z-2 (29 CFR 1910.1000) (02 2006)

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Biological Limit Values

Notogical Ellint 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: No data available. Odor: No data available. 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. No data available. Evaporation rate:

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Flammability (solid, gas): No data available.

Upper/lower limit on flammability or explosive limits

Flammability limit - upper (%):

Flammability limit - lower (%):

Explosive limit - upper (%):

Explosive limit - lower (%):

No data available.

No data available.

No data available.

Vapor pressure:

Vapor density:

No data available.

No data available.

No data available.

No data available.

Solubility(ies)

Solubility in water:
Solubility (other):
No data available.
Viscosity:
No data available.
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: No data available.

Dermal

Product: No data available.

Inhalation

Product: No data available.

Repeated dose toxicity

Product: not applicable

Skin Corrosion/Irritation

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

Serious Eye Damage/Eye Irritation

Product: No data available.

Respiratory or Skin Sensitization

Product: Not a skin sensitizer.

Carcinogenicity

Product: 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

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Germ Cell Mutagenicity

In vitro

Product: not applicable

In vivo

Product: not applicable

Reproductive toxicity

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

Specific Target Organ Toxicity - Single Exposure

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

Specific Target Organ Toxicity - Repeated Exposure

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

Aspiration Hazard

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

Other effects: None known.

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

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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.

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):

<u>Chemical Identity</u> <u>Reportable quantity</u>

Phosphoric acid, sodium 5000 lbs.

salt (1:2)

Sodium fluoride (NaF) 1000 lbs.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Not listed.

SARA 302 Extremely Hazardous Substance

None present or none present in regulated quantities.

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Becton, Dickinson and Company BD, Franklin Lakes, NJ 07417 USA www.bd.com

SARA 304 Emergency Release Notification

<u>Chemical Identity</u> <u>Reportable quantity</u>

Phosphoric acid, sodium 5000 lbs.

salt (1:2)

Ethanol, 2-phenoxy-

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)

Chemical Identity Reportable quantity

Phosphoric acid, sodium Reportable quantity: 5000 lbs.

salt (1:2)

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 regulated by CA Prop 65 present.

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: 09/21/2017

Version #: 2.1

Revision Information:

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Last revised date: 09/21/2017

Becton, Dickinson and Company BD, Franklin Lakes, NJ 07417 USA www.bd.com

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

Further Information: No data available.

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the completeness or accuracy of the information.

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