

SECTION 1: Identification

1.1. Identification

Product form : Article
Product name : Sofia Fluorescent Immunoassay Analyzer, Generation 1 and 2
Product code : 20221, 20299, 20300

1.2. Recommended use and restrictions on use

Recommended use : For medical diagnostic use.
Restrictions on use : Restricted to professional users, Professional Use of Medical Devices

1.3. Supplier

Manufacturer

Quidel Corporation
10165 McKellar Court
San Diego, CA 92121 - U.S.A
T 1.800.874.1517 - F 1.858.453.4338
gehs@quidelortho.com - quidel.com

1.4. Emergency telephone number

Emergency number : 1.866.519.4752

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. GHS Label elements, including precautionary statements

According to the corresponding national regulations there is no labelling obligation for this product.

2.3. Other hazards which do not result in classification

Other hazards which do not result in classification : Lithium ion battery may be contained or packed with the Sofia 2 instrument. These batteries are sealed units which are not hazardous when used according to the recommendations of the manufacturer. SDS available upon request.

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of HazCom 2012

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
First-aid measures after skin contact : Wash with water and soap. Wash skin with plenty of water.
First-aid measures after eye contact : Not expected to present a significant eye contact hazard under anticipated conditions of normal use. Rinse eyes with water as a precaution.
First-aid measures after ingestion : Not applicable. Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

Effects on humans : No additional information available.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Dry chemical powder. Foam.

5.2. Specific hazards arising from the chemical

Reactivity : The product is non-reactive under normal conditions of use, storage and transport.

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions : Depending on nature/size of load: consider extinguishment. Evacuate area.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Complete protective clothing.

Other information : This product is made up of hard plastic parts that will give off carbon monoxide and other toxic gases when burned. Use self contained breathing apparatus (SCBA) when fighting fires with this product involved.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear suitable protective clothing.

Emergency procedures : Only qualified personnel equipped with suitable protective equipment may intervene.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wear personal protective equipment. Ensure good ventilation of the work station.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store as directed in product literature.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available.

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment:

Gloves. Safety glasses.

Materials for protective clothing:

Lab coat

Hand protection:

Wear protective gloves. Wash your hands

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Not required for normal conditions of use

Personal protective equipment symbol(s):



Thermal hazard protection:

No data available.

Other information:

Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Instrument.
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability	: Non flammable.
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: Not applicable
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Viscosity, kinematic	: Not applicable

Viscosity, dynamic	: No data available
Explosion limits	: Not applicable
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Viscosity, kinematic	: Not applicable
Effects on humans	: No additional information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

- Regional legislation (waste) : Disposal must be done according to official regulations.
- Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
- Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
- Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

When a lithium ion battery is shipped with or included in the device itself, the information below is applicable.

Department of Transportation (DOT)

In accordance with DOT

- Transport document description (DOT) : UN3481 Lithium ion batteries contained in equipment, 9
- UN-No.(DOT) : UN3481
- Proper Shipping Name (DOT) : Lithium ion batteries contained in equipment
- Class (DOT) : 9 - Class 9 - Miscellaneous hazardous material 49 CFR 173.140
- Hazard labels (DOT) : 9 - Class 9 (Miscellaneous dangerous materials)



- DOT Packaging Non Bulk (49 CFR 173.xxx) : 185
- DOT Packaging Bulk (49 CFR 173.xxx) : 185

Sofia[®] Fluorescent Immunoassay Analyzer, Generation 1 and 2

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
 Issue date: 06/19/2019 Revision date: 03/15/2023 Supersedes: 07/05/2022 Version: 3.0

DOT Special Provisions (49 CFR 172.102) : 181 - When a package contains a combination of lithium batteries contained in equipment and lithium batteries packed with equipment, the following requirements apply: a. The shipper must ensure that all applicable requirements of §173.185 of this subchapter are met. The total mass of lithium batteries contained in any package must not exceed the quantity limits in columns (9A) and (9B) for passenger aircraft or cargo aircraft, as applicable; b. Except as provided in §173.185(c)(3) of this subchapter, the package must be marked "UN 3091 Lithium metal batteries packed with equipment", or "UN 3481 Lithium ion batteries packed with equipment," as appropriate. If a package contains both lithium metal batteries and lithium ion batteries packed with and contained in equipment, the package must be marked as required for both battery types. However, button cell batteries installed in equipment (including circuit boards) need not be considered; and c. The shipping paper must indicate "UN 3091 Lithium metal batteries packed with equipment" or "UN 3481 Lithium ion batteries packed with equipment," as appropriate. If a package contains both lithium metal batteries and lithium ion batteries packed with and contained in equipment, then the shipping paper must indicate both "UN 3091 Lithium metal batteries packed with equipment" and "UN 3481 Lithium ion batteries packed with equipment."
 388 - a. Lithium batteries containing both primary lithium metal cells and rechargeable lithium ion cells that are not designed to be externally charged, must meet the following conditions: i. The rechargeable lithium ion cells can only be charged from the primary lithium metal cells; ii. Overcharge of the rechargeable lithium ion cells is precluded by design; iii. The battery has been tested as a primary lithium battery; and iv. Component cells of the battery must be of a type proved to meet the respective testing requirements of the Manual of Tests and Criteria, part III, subsection 38.3 (IBR, see 171.7 of this subchapter). b. Lithium batteries conforming to paragraph a. of this special provision must be assigned to UN Nos. 3090 or 3091, as appropriate. When such batteries are transported in accordance with 173.185(c), the total lithium content of all lithium metal cells contained in the battery must not exceed 1.5 g and the total capacity of all lithium ion cells contained in the battery must not exceed 10 Wh.
 422 - When labelling is required, the label to be used must be the label shown in §172.447. Labels conforming to requirements in place on December 31, 2016 may continue to be used until December 31, 2018. When a placard is displayed, the placard must be the placard shown in §172.560.
 A54 - Lithium batteries or lithium batteries contained or packed with equipment that exceed the maximum gross weight allowed by Column (9B) of the 172.101 Table may only be transported on cargo aircraft if approved by the Associate Administrator.

DOT Packaging Exceptions (49 CFR 173.xxx) : 185
 DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : 5 kg
 DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : 35 kg
 DOT Vessel Stowage Location : A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel.
 Emergency Response Guide (ERG) Number : 147
 Other information : No supplementary information available.

Transport by sea

Transport document description (IMDG) : UN 3481 LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT, 9
 UN-No. (IMDG) : 3481
 Proper Shipping Name (IMDG) : LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT
 Class (IMDG) : 9 - Miscellaneous dangerous substances and articles
 Limited quantities (IMDG) : 0

Air transport

Transport document description (IATA) : UN 3481 Lithium ion batteries contained in equipment, 9A
UN-No. (IATA) : 3481
Proper Shipping Name (IATA) : Lithium ion batteries contained in equipment
Class (IATA) : 9 - Miscellaneous Dangerous Substances and Articles

SECTION 15: Regulatory information

15.1. US Federal regulations

No additional information available

15.2. International regulations

CANADA

EU-Regulations

National regulations

No additional information available

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date : 03/15/2023
Other information : Please review product insert prior to using this product.

SDS US Quidel

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.