

### SECTION 1: Identification

#### 1.1. Identification

Product form : Mixture  
 Product name : Sofia Influenza A+B FIA  
 Product code : 20218, 20254, 20284, 20289, 20306,

#### 1.2. Recommended use and restrictions on use

Recommended use : For medical diagnostic use.  
 Restrictions on use : 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](mailto:gehs@quidelortho.com) - [quidel.com](http://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

Components	GHS US classification
Reagent Tube (Extraction Reagent - Lyophilized)	Eye Dam. 1, H318

#### 2.2. GHS Label elements, including precautionary statements

##### GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Reagent Tube (Extraction Reagent - Lyophilized)		Danger	H318 - Causes serious eye damage	P280 - Wear lab coat, safety glasses, and gloves. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a poison center or doctor. P321 - Specific treatment: Seek medical attention if ill effect develops.

### SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Reagent Tube (Extraction Reagent - Lyophilized)	tetrasodium ethylenediaminetetracetate, dihydrate	10378-23-1	1 - 5	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318

Extraction solution is shipped as a lyophilized pellet and has a concentration of 3.067% EDTA, Tetrasodium Salt Dihydrate (10378-23-1). At this concentration H318 (Causes serious eye damage, Category 1) is applicable. When rehydrated following proper instructions, the EDTA concentration is 0.639%. At this concentration, H319 (Causes serious eye irritation, Category 2A) is applicable.

Full text of hazard classes and H-statements : see section 16

### 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.  
 First-aid measures after skin contact : Wash skin with plenty of water.  
 First-aid measures after eye contact : Rinse eyes with water as a precaution.  
 First-aid measures after ingestion : Call a poison center/doctor/physician if you feel unwell.

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

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 : Water spray. Dry powder. Foam.

### 5.2. Specific hazards arising from the chemical

No additional information available

### 5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

#### 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

Environmental precautions : Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product.

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

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 : Ensure good ventilation of the work station. Wear personal protective equipment.

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 in a well-ventilated place. Keep cool.

## 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

#### Materials for protective clothing:

Lab coat

#### Hand protection:

Protective gloves

#### Eye protection:

Safety glasses

**Respiratory protection:**

In case of insufficient ventilation, wear suitable respiratory equipment

**Personal protective equipment symbol(s):**



**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	: EIA Kit.	
Color	: Not applicable	
Odor	: Not applicable	
Odor threshold	: No data available	
pH	: Neutral	
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	: No data available	
Solubility	: No data available	
Partition coefficient n-octanol/water (Log Pow)	: No data available	
Auto-ignition temperature	: Not applicable	
Decomposition temperature	: No data available	
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

No additional information available

### 10.6. Hazardous decomposition products

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

## SECTION 11: Toxicological information

Acute toxicity (oral) : Not classified  
 Acute toxicity (dermal) : Not classified  
 Acute toxicity (inhalation) : Not classified

<b>tetrasodium ethylenediaminetetracetate, dihydrate (10378-23-1)</b>	
LD50 oral rat	1780 – 2000 mg/kg body weight (Rat, Male / female, Experimental value, Oral, 14 day(s))
ATE US (oral)	1780 mg/kg body weight

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

## 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.

### 12.2. Persistence and degradability

<b>tetrasodium ethylenediaminetetracetate, dihydrate (10378-23-1)</b>	
Persistence and degradability	Not readily biodegradable in water.

### 12.3. Bioaccumulative potential

<b>tetrasodium ethylenediaminetetracetate, dihydrate (10378-23-1)</b>	
BCF - Fish [1]	1.8 (28 day(s), Lepomis macrochirus, Flow-through system, Fresh water, Experimental value)
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).

### 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.  
 Sewage disposal recommendations : Disposal must be done according to official regulations.  
 Ecology - waste materials : Avoid release to the environment.

**SECTION 14: Transport information**
**Department of Transportation (DOT)**

Not regulated

**Transport by sea**

Not regulated

**Air transport**

Not regulated

**SECTION 15: Regulatory information**
**15.1. US Federal regulations**
**Sofia Influenza A+B FIA**

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

tetrasodium ethylenediaminetetracetate, dihydrate	CAS No 10378-23-1	1 – 5%
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This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

**15.2. International regulations**
**CANADA**
**tetrasodium ethylenediaminetetracetate, dihydrate (10378-23-1)**

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

**EU-Regulations**

No additional information available

**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

**Indication of changes:**

Regulatory Review. Updated SDS template. Composition/Information on ingredients.

*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.*