

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

**1.1. Product identifier**

Product form : Mixture  
 Product name : Sofia Quantitative Vitamin D FIA  
 Product code : 20282  
 Product group : Kit

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

**1.2.1. Relevant identified uses**

Industrial/Professional use spec : For in vitro diagnostic use

**1.2.2. Uses advised against**

Restrictions on use : Professional Use of Medical Devices

**1.3. Details of the supplier of the safety data sheet**

Quidel Corporation  
 10165 McKellar Court  
 92121 San Diego, CA - U.S.A  
 T 1.800.874.1517 - F 1.858.453.4338  
[gehs@quidel.com](mailto:gehs@quidel.com) - [quidel.com](http://quidel.com)

**1.4. Emergency telephone number**

Emergency number : 1.866.519.4752

**SECTION 2: Hazards identification**

**2.1. Classification of the substance or mixture**

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

Components	CLP classification
Extraction Solution	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT RE 2, H373


Full text of H- and EUH-statements: see section 16

**Adverse physicochemical, human health and environmental effects**

May cause damage to organs through prolonged or repeated exposure. Causes skin irritation. Causes serious eye damage.

**2.2. Label elements**

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements	Extra phrases
Extraction Solution		Danger	H315 - Causes skin irritation. H318 - Causes serious eye damage. H373 - May cause damage to organs through prolonged or repeated exposure.	P280 - Wear lab coat, safety glasses, and gloves. P302+P352 - IF ON SKIN: Wash with plenty of water. 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 (see supplemental first aid instruction on this label).	No additional information available

**2.3. Other hazards**

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Chemical name	CAS No EC-No.	%	CLP classification
Extraction Solution	sodium metaperiodate	7790-28-5 -	4.7	Ox. Sol. 1, H271 Skin Corr. 1C, H314 Eye Dam. 1, H318 STOT RE 1, H372 Aquatic Acute 1, H400

Full text of H- and EUH-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: Get medical advice/attention if you feel unwell.
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. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact	: Irritation.
Symptoms/effects after eye contact	: Serious damage to eyes.

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

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

#### 5.3. Advice for firefighters

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. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.

##### 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

Methods for cleaning up : Take up liquid spill into absorbent material.  
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 : Ensure good ventilation of the work station. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes. Wear personal protective equipment.

Hygiene measures : Wash contaminated clothing before reuse. 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.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### 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):



#### Environmental exposure controls:

Avoid release to the environment.

#### 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 : Liquid  
 Colour : No data available  
 Odour : Odorless.  
 Odour threshold : No data available  
 pH : 4.5  
 Relative evaporation rate (butylacetate=1) : No data available  
 Melting point : Not applicable  
 Freezing point : No data available  
 Boiling point : No data available

Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability	: Not applicable
Vapour pressure	: No data available
Relative vapour density at 20°C	: No data available
Relative density	: No data available
Solubility	: Soluble.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: 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

### 11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Causes skin irritation. pH: 4.5
Serious eye damage/irritation	: Causes serious eye damage. pH: 4.5
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

sodium metaperiodate (7790-28-5)	
LC50 - Fish [1]	> 0.17 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Oncorhynchus mykiss, Semi-static system, Fresh water, Experimental value)
EC50 - Crustacea [1]	0.18 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value)
ErC50 algae	1.1 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value)

#### 12.2. Persistence and degradability

sodium metaperiodate (7790-28-5)	
Persistence and degradability	Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable

#### 12.3. Bioaccumulative potential

sodium metaperiodate (7790-28-5)	
Partition coefficient n-octanol/water (Log Pow)	-1 (20 °C)
Bioaccumulative potential	Not bioaccumulative.

#### 12.4. Mobility in soil

sodium metaperiodate (7790-28-5)	
Ecology - soil	No (test) data on mobility of the substance available.

#### 12.5. Results of PBT and vPvB assessment

Component	
sodium metaperiodate (7790-28-5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

#### 12.6. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment 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

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

### 14.1. UN number

UN-No. (ADR)	: Not regulated
UN-No. (IMDG)	: Not regulated
UN-No. (IATA)	: Not regulated
UN-No. (ADN)	: Not regulated
UN-No. (RID)	: Not regulated

### 14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not regulated
Proper Shipping Name (IMDG)	: Not regulated
Proper Shipping Name (IATA)	: Not regulated
Proper Shipping Name (ADN)	: Not regulated
Proper Shipping Name (RID)	: Not regulated

### 14.3. Transport hazard class(es)

#### ADR

Transport hazard class(es) (ADR)	: Not regulated
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#### IMDG

Transport hazard class(es) (IMDG)	: Not regulated
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#### IATA

Transport hazard class(es) (IATA)	: Not regulated
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#### ADN

Transport hazard class(es) (ADN)	: Not regulated
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#### RID

Transport hazard class(es) (RID)	: Not regulated
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### 14.4. Packing group

Packing group (ADR)	: Not regulated
Packing group (IMDG)	: Not regulated
Packing group (IATA)	: Not regulated
Packing group (ADN)	: Not regulated
Packing group (RID)	: Not regulated

### 14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

#### Rail transport

Not regulated

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

### SECTION 15: Regulatory information

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

##### 15.1.1. EU-Regulations

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

Contains no substance(s) listed on the REACH Candidate List

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

##### 15.1.2. National regulations

###### Germany

Regulatory reference : WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1)

Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG)

Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

###### Netherlands

SZW-lijst van kankerverwekkende stoffen : sodium metaperiodate is listed

SZW-lijst van mutagene stoffen : sodium metaperiodate is listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

###### Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product  
 Pregnant/breastfeeding women working with the product must not be in direct contact with the product

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

Indication of changes:	
Regulatory Review.	
Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BLV	Biological limit value
CAS No	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
EN	European Standard
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration

LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
vPvB	Very Persistent and Very Bioaccumulative
WGK	Water Hazard Class

Other information : Please review product insert prior to using this product.

<b>Full text of H- and EUH-statements:</b>	
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H271	May cause fire or explosion; strong oxidiser.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
Ox. Sol. 1	Oxidising Solids, Category 1
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

*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.*