

# according to Regulation (EC) No 1907/2006

# VA Reagent

Revision date: 24.11.2022

Product code:

Page 1 of 11

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

# 1.1. Product identifier

VA Reagent

Further trade names Article No.: 1894718

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

Use of the substance/mixture

Scientific research and development, in vitro diagnostic medical devices

#### Uses advised against

Any non-intended use.

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

Company name:	Hain Lifescience GmbH	
Street:	Hardwiesenstrasse 1	
Place:	D-72147 Nehren	
Telephone:	+49 (0) 74 73- 94 51- 0	Telefax: +49 (0) 74 73- 94 51- 31
Responsible Department:	msds.mdx.de@bruker.com	
1.4. Emergency telephone	Poison Information Center Mainz, Ge	ermany, Tel: +49(0)6131/19240

#### number:

# Further Information

The product falls under the regulation (EU) 2017/746 on in-vitro diagnostics.

# **SECTION 2: Hazards identification**

# 2.1. Classification of the substance or mixture

# Regulation (EC) No 1272/2008

Acute Tox. 4; H302 Acute Tox. 4; H332 Skin Irrit. 2; H315 Eye Irrit. 2; H319

Full text of hazard statements: see SECTION 16.

# 2.2. Label elements

## Regulation (EC) No 1272/2008

# Hazard components for labelling

guanidinium chloride; guanadine hydrochloride

Signal word: Pictograms:

Warning



#### Hazard statements

H302+H332	Harmful if swallowed or if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
Precautionary state	ments
5004	

1.



according to Regulation (EC) No 1907/2006

# VA Reagent

Revision date: 24.11.2022	Product code:	Page 2 of 11
P302+P352	IF ON SKIN: Wash with plenty of water.	
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	

#### Additional advice on labelling

Labelling according to national medical devices regulations.

# 2.3. Other hazards

The substances in the mixture (>0,1%) do not meet the PBT/vPvB criteria according to REACH, annex XIII. This product does not contain a substance (> 0,1 %) that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

#### **SECTION 3: Composition/information on ingredients**

## 3.2. Mixtures

## Hazardous components

CAS No	Chemical name			Quantity	
	EC No	Index No	REACH No		
	GHS Classification				
50-01-1	guanidinium chloride; gu	anadine hydrochloride	ochloride		
	200-002-3	607-148-00-0	01-2119977063-35		
	Acute Tox. 4, Acute Tox.	. 4, Skin Irrit. 2, Eye Irrit. 2; H332 H30	t. 2, Eye Irrit. 2; H332 H302 H315 H319		

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

# Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
Specific Conc. Limits, M-factors and ATE			
50-01-1	200-002-3	guanidinium chloride; guanadine hydrochloride	40 - < 45 %
inhalation: ATE = 11 mg/l (vapours); inhalation: LC50 = 5,32 mg/l (dusts or mists); dermal: LD50 = >2000 mg/kg; oral: LD50 = 773,6 mg/kg			

#### **Further Information**

Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

## **SECTION 4: First aid measures**

# 4.1. Description of first aid measures

#### General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

#### After inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

#### After contact with skin

Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

#### After contact with eyes

Rinse cautiously with water for several minutes. In case of troubles or persistent symptoms, consult an ophthalmologist.

# After ingestion

Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.

according to Regulation (EC) No 1907/2006

# **VA Reagent**

Revision date: 24.11.2022

# Product code:

Page 3 of 11

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

No information available.

# 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

Carbon dioxide (CO2). Dry extinguishing powder. alcohol resistant foam. Atomized water.

# Unsuitable extinguishing media

High power water jet.

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

Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO2).

#### 5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

# Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Co-ordinate fire-fighting measures to the fire surroundings.

#### **SECTION 6: Accidental release measures**

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

#### General advice

Safe handling: see section 7

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

#### For emergency responders

No special measures are necessary.

#### 6.2. Environmental precautions

Discharge into the environment must be avoided.

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

# For containment

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

#### For cleaning up

Clean contaminated objects and areas thoroughly observing environmental regulations.

#### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

## **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

#### Advice on safe handling

Wear suitable protective clothing. See section 8.

#### Advice on protection against fire and explosion Usual measures for fire prevention.

Osual measures for the prevention.

# Advice on general occupational hygiene

Always close containers tightly after the removal of product. Do not eat, drink, smoke or sneeze at the



according to Regulation (EC) No 1907/2006

# VA Reagent

Revision date: 24.11.2022

Product code:

Page 4 of 11

workplace. Wash hands before breaks and after work.

# Further information on handling

General protection and hygiene measures: See section 8.

# 7.2. Conditions for safe storage, including any incompatibilities

# Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place.

#### Hints on joint storage

Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and animal feedingstuff.

#### Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity. Recommended storage temperature: 20°C Protect against: frost. UV-radiation/sunlight. heat. Humidity

#### 7.3. Specific end use(s)

See section 1.

# **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

#### **PNEC** values

CAS No	Substance	
Environmental compartment		Value
50-01-1 guanidinium chloride; guanadine hydrochloride		
Freshwater		0,29 mg/l
Marine water		0,029 mg/l
Freshwater sediment		1,08 mg/kg
Marine sediment		0,108 mg/kg
Micro-organisn	ns in sewage treatment plants (STP)	7125 mg/l
Soil		4,35 mg/kg

# Additional advice on limit values

To date, no national critical limit values exist.

## 8.2. Exposure controls





#### Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.

Provide adequate ventilation.

Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses; chemical goggles (if splashing is possible). EN 166

## Hand protection

Wear suitable gloves. Suitable material: FKM (fluororubber). - Thickness of glove material: 0,4 mm Breakthrough time >= 8 h



according to Regulation (EC) No 1907/2006

# VA Reagent

Revision date: 24.11.2022

Product code:

Page 5 of 11

Butyl rubber. - Thickness of glove material: 0,5 mm

Breakthrough time >= 8 h CR (polychloroprenes, Chloroprene rubber). - Thickness of glove material: 0,5 mm

Breakthrough time >= 8 h

NBR (Nitrile rubber). - Thickness of glove material: 0,35 mm

Breakthrough time  $\geq 8$  h

PVC (Polyvinyl chloride). - Thickness of glove material: 0,5 mm

Breakthrough time >= 8 h

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

The selected protective gloves have to satisfy the specifications of EU Directive EC/2016/425 and the standard EN 374 derived from it.

Check leak tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well.

# Skin protection

Suitable protective clothing: Lab apron.

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500 (D).

## **Respiratory protection**

With correct and proper use, and under normal conditions, breathing protection is not required.

Respiratory protection necessary at:

-Exceeding exposure limit values

-Insufficient ventilation and aerosol or mist formation

Suitable respiratory protective equipment: particulates filter device (DIN EN 143). type: P1-3

The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

#### **Environmental exposure controls**

Do not allow uncontrolled discharge of product into the environment.

# **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

Physical state: Colour: Odour: Odour threshold:	liquid colourless characteristic not determined	
Changes in the physical state		
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		not determined
Sublimation point:		not determined
Softening point:		not determined
Pour point:		not determined
Flash point:		not determined
Flammability Solid/liquid:		not determined
Explosive properties none		
Lower explosion limits:		not determined
Upper explosion limits:		not determined



according to Regulation (EC) No 1907/2006

	VA Reagent	
Revision date: 24.11.2022	Product code:	Page 6 of 11
Auto-ignition temperature:	not determined	
Self-ignition temperature		
Solid:	not relevant	
Gas:	not relevant	
Decomposition temperature:	not determined	
pH-Value:	not determined	
Viscosity / dynamic:	not determined	
Viscosity / kinematic:	not determined	
Flow time:	not determined	
Water solubility:	not determined	
Solubility in other solvents not determined		
Dissolution rate:	not relevant	
Partition coefficient n-octanol/water:	SECTION 12: Ecological information	
Dispersion stability:	not relevant	
Vapour pressure:	not determined	
Density:	not determined	
Bulk density:	not determined	
Relative vapour density:	not determined	
Particle characteristics:	not relevant	
9.2. Other information		
Information with regard to physical hazard classes Sustaining combustion:	Not sustaining combustion	
Oxidizing properties	Not sustaining compustion	
none		
Other safety characteristics		
Solvent separation test:	not determined	
Solvent content:	not determined	
Solid content:	not determined	
Evaporation rate:	not determined	
-		

No information available.

# SECTION 10: Stability and reactivity

# 10.1. Reactivity

No information available.

# 10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

# 10.3. Possibility of hazardous reactions

Refer to chapter 10.5.

# 10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

# 10.5. Incompatible materials

Materials to avoid: Oxidizing agents, strong. Reducing agents, strong.

according to Regulation (EC) No 1907/2006

# VA Reagent

Revision date: 24.11.2022

Product code:

Page 7 of 11

# 10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

# **SECTION 11: Toxicological information**

# 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

# Toxicocinetics, metabolism and distribution

No data available.

#### Acute toxicity

Harmful if swallowed. Harmful if inhaled.

# ATEmix calculated

ATE (oral) 1934,0 mg/kg; ATE (inhalation dust/mist) 3,750 mg/l

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
50-01-1	guanidinium chloride; guanadine hydrochloride					
	oral	LD50 mg/kg	773,6	Rat, female.	ECHA Dossier	EPA TS-792 A
	dermal	LD50 mg/kg	>2000	Rabbit	ECHA Dossier	
	inhalation vapour	ATE	11 mg/l			
	inhalation (4 h) dust/mist	LC50	5,32 mg/l	Rat	ECHA Dossier	

## Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

# Sensitising effects

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

#### Carcinogenic/mutagenic/toxic effects for reproduction

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

## STOT-single exposure

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

#### STOT-repeated exposure

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

#### Aspiration hazard

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

#### Specific effects in experiment on an animal

No data available.

# 11.2. Information on other hazards

## **Endocrine disrupting properties**

This product does not contain a substance (> 0,1 %) that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

#### Other information

No data available.

# **SECTION 12: Ecological information**

# 12.1. Toxicity

The product has not been tested.



# according to Regulation (EC) No 1907/2006

# VA Reagent

Revision date: 24.11.2022

Product code:

Page 8 of 11

CAS No	Chemical name				
	Aquatic toxicity	Dose	[h]   [d] Species	Source	Method
50-01-1	guanidinium chloride; guanadine hydrochloride				
	Acute fish toxicity	LC50 1758 mg/l	96 h Leucisus idus	ECHA Dossier	

## 12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
50-01-1	guanidinium chloride; guanadine hydrochloride			
	OECD 301C / ISO 9408 / EEC 92/69 annex V, C.4-F	0	56	ECHA Dossier

#### 12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

# Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
50-01-1	guanidinium chloride; guanadine hydrochloride	

# 12.4. Mobility in soil

No data available.

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

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII. The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

#### 12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%

#### 12.7. Other adverse effects

No data available.

# **Further information**

Do not allow to enter into surface water or drains.

# SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

#### **Disposal recommendations**

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal. Non-contaminated packages may be recycled.

According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.

Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

# List of Wastes Code - residues/unused products

160305 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; off-specification batches and unused products; organic wastes containing hazardous substances; hazardous waste

#### List of Wastes Code - used product



	according to Regulation (EC) No 1907/2006			
VA Reagent				
Revision date: 24.11.2022	Product code:	Page 9 of 11		
160305 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; off-specification batches and unused products; organic wastes containing hazardous substances; hazardous waste				
150110 WASTE PACKAGING; A PROTECTIVE CLOTHIN collected municipal pack	Wastes Code - contaminated packaging   110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND   PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste			
<b>Contaminated packaging</b> Handle contaminated packages in the same way as the substance itself.				
SECTION 14: Transport information				
Land transport (ADR/RID)				
14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.			
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.			
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.			
14.4. Packing group:	No dangerous good in sense of this transport regulation.			
Inland waterways transport (ADN)				
14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.			
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.			
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.			
14.4. Packing group:	No dangerous good in sense of this transport regulation.			
Marine transport (IMDG)				
<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.			
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.			
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.			
14.4. Packing group:	No dangerous good in sense of this transport regulation.			
Air transport (ICAO-TI/IATA-DGR)	··· ··································			
<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.			
<u>14.2. UN proper shipping name:</u> 14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.			
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.			
	No dangerous good in sense of this transport regulation.			
14.5. Environmental hazards ENVIRONMENTALLY HAZARDOUS:	No			
14.6. Special precautions for user				
refer to chapter 6 - 8	a to IMO instruments			
14.7. Maritime transport in bulk according to IMO instruments not relevant				
SECTION 15: Regulatory information				
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture				
EU regulatory information				
Restrictions on use (REACH, annex XVII):				
Entry 3, Entry 75				

2010/75/EU (VOC): No information available. 2004/42/EC (VOC): No information available.



# according to Regulation (EC) No 1907/2006

VA Reagent				
Revision date: 24.11.2022	Product code:	Page 10 of 11		
Information according to 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)			
Additional information				
Safety Data Sheet according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 2020/878) The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP]. REACH 1907/2006 Appendix XVII, No (mixture): 3				
National regulatory information				
Employment restrictions:	Observe restrictions to employment for juveniles ac work protection guideline' (94/33/EC).	cording to the 'juvenile		

Water hazard class (D):

1 - slightly hazardous to water

# 15.2. Chemical safety assessment

For the following substances of this mixture a chemical safety assessment has been carried out:

# **SECTION 16: Other information**

# Changes

Rev. 1.0; Initial release: 24.01.2022 Rev. 2.0; Revision: 24.11.2022

#### Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) AGW: Arbeitsplatzgrenzwert CAS: Chemical Abstracts Service CLP: Classification, Labelling and Packaging of substances and mixtures DNEL: Derived No Effect Level d: day(s) EINECS: European INventory of Existing Commercial chemical Substances ELINCS: European LIst of Notified Chemical Substances ECHA: European Chemicals Agency EWC: European Waste Catalogue IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA) ICAO: International Civil Aviation Organization ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO) GHS: Globally Harmonized System of Classification and Labelling of Chemicals GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany) h. pour LOAEL: Lowest observed adverse effect level LOAEC: Lowest observed adverse effect concentration LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent NOAEL: No observed adverse effect level NOAEC: No observed adverse effect concentration NLP: No-Longer Polymers N/A: not applicable OECD: Organisation for Economic Co-operation and Development PNEC: predicted no effect concentration PBT: Persistent bioaccumulative toxic RID: Regulation Concerning the International Transport of Dangerous Goods by Rail REACH: Registration, Evaluation, Authorisation of Chemicals SVHC: substance of very high concern TRGS: Technische Regeln für Gefahrstoffe



according to Regulation (EC) No 1907/2006

# VA Reagent

Revision date: 24.11.2022

Product code:

Page 11 of 11

#### UN: United Nations VOC: Volatile Organic Compounds

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Acute Tox. 4; H302	Calculation method
Acute Tox. 4; H332	Calculation method
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method

# Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H302+H332	Harmful if swallowed or if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.

# **Further Information**

Classification according to Regulation (EC) No 1272/2008 [CLP] - Classification procedure:

Health hazards: Calculation method.

Environmental hazards: Calculation method.

Physical hazards: On basis of test data and / or calculated and / or estimated.

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)