## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Issue date: 7/6/2022 Revision date: 7/6/2022 Supersedes: 5/14/2021 Version: 3.0

SDS No: 13129-0020



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

#### 1.1. Product identifier

Product form : Mixture

Product name : Instru Zym Bio-wipes UFI : A9R0-A0TY-E002-3TSA

Type of product : Detergent

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

#### 1.2.1. Relevant identified uses

Use of the substance/mixture : Instrument cleaner

Medical devices

#### 1.2.2. Uses advised against

No additional information available

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

Laboratorium Dr. Deppe GmbH

Hooghe Weg 35 47906 Kempen Germany

T +49 2152 55650 - F +49 2152 50849 sdb@drdeppe.de - www.drdeppe.de

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

#### 1.4. Emergency telephone number

Emergency number : INTERNATIONAL: +49 6132 84463, GBK GmbH (24 h - 7 d/w - 365 d/a)

#### **SECTION 2: Hazards identification**

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

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

Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412

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

## Adverse physicochemical, human health and environmental effects

Harmful to aquatic life with long lasting effects.

## 2.2. Label elements

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

Signal word (CLP) : -

Hazard statements (CLP) : H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) : P273 - Avoid release to the environment.

P501 - Dispose of contents and container to in accordance with local and national

regulations.

#### 2.3. Other hazards

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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 SDS No: 13129-0020

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

#### 3.1. Substances

Not applicable

## 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides	CAS-No.: 68424-85-1 EC-No.: 270-325-2 REACH-no: 01-2119965180- 41	≥ 0.3 – < 1	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
didecyldimethylammonium chloride	CAS-No.: 7173-51-5 EC-No.: 230-525-2 EC Index-No.: 612-131-00-6 REACH-no: 01-2119945987- 15	≥ 0.1 – < 0.5	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 2, H411

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 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 or a doctor if you feel unwell.

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

Symptoms/effects : When used and handled according to specifications, the product does not have any harmful

effects according to our experience and the information provided to us.

## 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.

Unsuitable extinguishing media : Strong water jet.

#### 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.

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SDS No: 13129-0020

#### **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

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. 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.

## 7.3. Specific end use(s)

See Section 1.

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

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

## 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

### 8.1.5. Control banding

No additional information available

#### 8.2. Exposure controls

## 8.2.1. Appropriate engineering controls

## Appropriate engineering controls:

Ensure good ventilation of the work station.

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 SDS No: 13129-0020

#### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

#### Eye protection:

Use splash goggles when eye contact due to splashing is possible

#### 8.2.2.2. Skin protection

#### Skin and body protection:

No specific measures are necessary

#### Hand protection:

Not required for normal conditions of use. Nitrile rubber gloves

#### 8.2.2.3. Respiratory protection

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

#### **Environmental exposure controls:**

Avoid release to the environment.

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

#### 9.1. Information on basic physical and chemical properties

Physical state : Liquid Colour yellowish

Appearance Clothes impregnated with alcolholic disinfectant

Odour : Not available Odour threshold : Not available : Not available Melting point Freezing point : Not available : > 100 °C Boiling point : Non flammable. Flammability **Explosive limits** : Not available Lower explosive limit (LEL) : Not available Upper explosive limit (UEL) : Not available Flash point : > 60 °C Auto-ignition temperature : Not available Decomposition temperature : Not available

: 6 рΗ

Viscosity, kinematic : Not available Solubility : Not available Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available Vapour pressure at 50 °C : Not available Density : 1.015 - 1.26 g/ml : Not available Relative density Relative vapour density at 20 °C : Not available Particle characteristics : Not applicable

## 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

### 9.2.2. Other safety characteristics

No additional information available

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 SDS No: 13129-0020

## **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

Oxidizing agent.

## 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 hazard classes as defined in Regulation (EC) No 1272/2008

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

Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides (68424-85-1)		
LD50 oral rat 795 mg/kg		
LD50 dermal rabbit	≈ 3412 mg/kg	
ATE CLP (oral) 500 mg/kg bodyweight		

## didecyldimethylammonium chloride (7173-51-5)

ATE CLP (oral)	500 mg/kg bodyweight	
Skin corrosion/irritation	· Not classified	

pH: 6 : Not classified Serious eye damage/irritation

pH: 6

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 : Not classified Aspiration hazard : Not classified

### 11.2. Information on other hazards

No additional information available

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 SDS No: 13129-0020

## **SECTION 12: Ecological information**

#### 12.1. Toxicity

: Harmful to aquatic life with long lasting effects. Ecology - general

Hazardous to the aquatic environment, short-term : Not classified

Hazardous to the aquatic environment, long-term

: Harmful to aquatic life with long lasting effects.

(chronic)

## 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. Results of PBT and vPvB assessment

No additional information available

#### 12.6. Endocrine disrupting properties

No additional information available

## 12.7. Other adverse effects

No additional information available

## **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

## **SECTION 14: Transport information**

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

ADR	IMDG	IATA	ADN	RID	
14.1. UN number or ID n	14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated	
14.2. UN proper shippin	g name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated	
14.3. Transport hazard o	14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated	
14.4. Packing group					
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated	
14.5. Environmental hazards					
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated	
No supplementary information available					

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 SDS No: 13129-0020

#### 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. Maritime transport in bulk according to IMO instruments

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

EU restriction list (REACH Annex XVII)			
Reference code	Applicable on	Entry title or description	
3(b)	Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	
3(c)	Instru Zym Bio-wipes; Quaternary ammonium compounds, benzyl-C12- 16-alkyldimethyl, chlorides	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1	

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Substances subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 july 2012 concerning the export and import of hazardous chemicals: Didecyldimethylammonium chloride (7173-51-5)

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

#### Allergenic fragrances > 0,01%:

**D-LIMONENE** 

## **Detergent Regulation (648/2004/EC): Labelling of contents:**

Component

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on drug precursors)

7/6/2022 (Revision date) EU - en 7/10

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 SDS No: 13129-0020

## 15.1.2. National regulations

No additional information available

# 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## **SECTION 16: Other information**

Indication of changes			
Section Changed item Change Comments			
		Modified	

Abbreviations and ac	cronyms:		
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		
BCF	Bioconcentration factor		
BLV	Biological limit value		
BOD	Biochemical oxygen demand (BOD)		
COD	Chemical oxygen demand (COD)		
DMEL	Derived Minimal Effect level		
DNEL	Derived-No Effect Level		
EC-No.	European Community number		
EC50	Median effective concentration		
EN	European Standard		
IARC	International Agency for Research on Cancer		
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		
OECD	Organisation for Economic Co-operation and Development		
OEL	Occupational Exposure Limit		
PBT	Persistent Bioaccumulative Toxic		
PNEC	Predicted No-Effect Concentration		
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail		
SDS	Safety Data Sheet		
STP	Sewage treatment plant		

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 SDS No: 13129-0020

Abbreviations and acronyms:			
ThOD	Theoretical oxygen demand (ThOD)		
TLM	Median Tolerance Limit		
VOC	Volatile Organic Compounds		
CAS-No.	Chemical Abstract Service number		
N.O.S.	Not Otherwise Specified		
vPvB	Very Persistent and Very Bioaccumulative		
ED	Endocrine disrupting properties		
DOT	Department of Transport		
TDG	Transportation of Dangerous Goods		
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006		
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals		
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk		
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008		
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships		
ADG	Transport of Australian Dangerous Goods		

Other information

: Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

Full text of H- and EUH-statements:			
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4		
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1		
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1		
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2		
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3		
Eye Dam. 1	Serious eye damage/eye irritation, Category 1		
H302	Harmful if swallowed.		
H314	Causes severe skin burns and eye damage.		
H318	Causes serious eye damage.		
H400	Very toxic to aquatic life.		
H410	Very toxic to aquatic life with long lasting effects.		
H411	Toxic to aquatic life with long lasting effects.		
H412	Harmful to aquatic life with long lasting effects.		
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B		

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Aquatic Chronic 3	H412	Calculation method

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 SDS No: 13129-0020

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 therefore not be construed as guaranteeing any specific property of the product.