

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

1.1 Product identifier

Trade name: Urine QC 1-3

UFI: HF90-10X4-G008-M81W

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

Application of the substance / the mixture

Quality control material - For research use only. Not for use in diagnostic procedures.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

biocrates life sciences ag

Eduard-Bodem-Gasse 8

A-6020 Innsbruck

T: +43 512 57 98 23

F:+43 512 57 98 23 329

Further information obtainable from: Email: office@biocrates.com

1.4 Emergency telephone number:

+43 512 57 98 23

Available during office hours:

Mo-Fr: 9 a.m. - 5 p.m.

Call the national emergency number!

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Eye Dam. 1 H318 Causes serious eye damage.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Additional information: For the wording of the hazard categories, see section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS05

GHS07

Signal word Danger

Hazard-determining components of labelling:

indole

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Hazard statements

H318 Causes serious eye damage.

H317 May cause an allergic skin reaction.

Precautionary statements

P261 Avoid breathing dust.

P280 Wear protective gloves / eye protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and 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/doctor.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards Dust can cause irritation of eyes, skin, nose and throat through mechanical friction.

Results of PBT and vPvB assessment

PBT: No data available.

vPvB: No data available.

Determination of endocrine-disrupting properties

The product does not contain substances with endocrine-disrupting properties ≥ 0.1 %(w/w).

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description:

Urine dry mass with additives.

Mixture of substances listed below with nonhazardous additions.

Dangerous components:

[% (w/w)]

CAS: 120-72-9	indole	3 - < 5%
EINECS: 204-420-7	 Acute Tox. 3, H311	
RTECS: NL 2450000	 Eye Dam. 1, H318	
	 Acute Tox. 4, H302; Skin Sens. 1, H317	

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of discomfort or doubt, seek medical advice.

If unconscious, use a stable lateral position and do not administer anything through mouth.

After inhalation:

Supply fresh air.

In case of unconsciousness place patient stably in side position for transportation.

After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment in case of complaints.

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After eye contact:

Rinse opened eye for several minutes under running water. Then consult a doctor.
Do not rub the eye dry, as mechanical friction can also cause corneal damage.
Consult an ophthalmologist or eye clinic immediately.

After swallowing:

Rinse mouth.
Call for a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

Depending on the condition of the patients, the doctor must assess the symptoms and the overall general condition.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

For safety reasons unsuitable extinguishing agents: Water with full jet

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

CO_x

Nitrogen oxides (NO_x)

5.3 Advice for firefighters

Protective equipment:

Wear self-contained respiratory protective device.
Wear fully protective suit.

Additional information

Collect contaminated fire fighting water separately. It must not enter the sewage system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Restricted access to the affected area until cleaning work is completed.

Wear protective equipment. Keep unprotected persons away.

Ensure adequate ventilation

Avoid contact with skin and eyes.

Avoid breathing dust.

Keep away from ignition sources.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

Avoid the formation of dust.

Dispose of the material collected according to regulations.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.

Keep receptacles tightly sealed.

Avoid contact with skin and eyes.

Prevent formation of dust.

Do not breathe dust.

Eye wash bottles and emergency showers should be provided in the immediate area near the workplace.

Use personal protective equipment as required.

Information about fire - and explosion protection:

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

7.2 Conditions for safe storage, including any incompatibilities**Storage:****Requirements to be met by storerooms and receptacles:**

Store in a dry, cool, well-ventilated area.

Store in accordance with local/regional/national/international regulations.

Information about storage in one common storage facility: Store away from incompatible materials.

Further information about storage conditions:

Keep container tightly sealed.

Store in dry conditions.

Storage class: 11

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

DNELs No data available.

PNECs No data available.

Regulatory information**Additional Occupational Exposure Limit Values for possible hazards during processing:**

The national dust limits must be observed in the event of dust generation.

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Appropriate engineering controls No further data; see section 7.

Individual protection measures, such as personal protective equipment**General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

Do not eat, drink, smoke or sniff while working.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

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Avoid breathing dust.

Immediately remove all soiled and contaminated clothing.

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Eye wash bottles and emergency showers should be provided in the immediate area near the workplace.

Respiratory protection: Wear respiratory protection during dust formation.

Hand protection

Protective gloves

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye/face protection

Tightly sealed goggles

Body protection: Protective work clothing

Environmental exposure controls

Inform respective authorities in case of seepage into water course or sewage system.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties****General Information**

Physical state	Solid
Colour:	Light yellow
Odour:	Odourless
Odour threshold:	No information available.
Melting point/freezing point:	No information available.
Boiling point or initial boiling point and boiling range	No information available.
Flammability	No information available.
Lower and upper explosion limit	
Lower:	No information available.
Upper:	No information available.

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Flash point:	Not applicable.
Decomposition temperature:	No information available.
pH	Not applicable.
Viscosity:	
Kinematic viscosity	Not applicable.
Dynamic:	Not applicable.
Solubility	
water:	No information available.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not applicable.
Density and/or relative density	
Density:	No information available.
Vapour density	Not applicable.
Particle characteristics	See section 3.

9.2 Other information**Appearance:**

Form: Solid

Important information on protection of health and environment, and on safety.

Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Change in condition	
Oxidising properties	No information available.
Evaporation rate	No information available.

Information with regard to physical hazard classes

Explosives	void
Flammable gases	void
Aerosols	void
Oxidising gases	void
Gases under pressure	void
Flammable liquids	void
Flammable solids	void
Self-reactive substances and mixtures	void
Pyrophoric liquids	void
Pyrophoric solids	void
Self-heating substances and mixtures	void
Substances and mixtures, which emit flammable gases in contact with water	void
Oxidising liquids	void
Oxidising solids	void
Organic peroxides	void
Corrosive to metals	void

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Desensitised explosives

void

SECTION 10: Stability and reactivity**10.1 Reactivity** No further relevant information available.**10.2 Chemical stability** No decomposition if used and stored according to specifications.**10.3 Possibility of hazardous reactions** Dust can combine with air to form an explosive mixture.**10.4 Conditions to avoid**

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5 Incompatible materials: No further relevant information available.**10.6 Hazardous decomposition products:** No dangerous decomposition products known.**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity** Based on available data, the classification criteria are not met.**LD/LC50 values relevant for classification:****ATE (Acute Toxicity Estimates)**

Oral	LD50	24,388 mg/kg (rat)
Dermal	LD50	19,267 mg/kg (Rabbit)

CAS: 120-72-9 indole

Oral	LD50	1,000 mg/kg (rat)
Dermal	LD50	790 mg/kg (Rabbit)

Primary irritant effect:**Skin corrosion/irritation** Based on available data, the classification criteria are not met.**Serious eye damage/irritation**

Causes serious eye damage.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity Based on available data, the classification criteria are not met.**Carcinogenicity** Based on available data, the classification criteria are not met.**Reproductive toxicity** 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.**11.2 Information on other hazards****Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information**12.1 Toxicity****Aquatic toxicity:** No further relevant information available.

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12.2 Persistence and degradability No further relevant information available.**12.3 Bioaccumulative potential** No further relevant information available.**12.4 Mobility in soil** No further relevant information available.**12.5 Results of PBT and vPvB assessment****PBT:** No data available.**vPvB:** No data available.**12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects**Additional ecological information:****General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow product to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations**13.1 Waste treatment methods****Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Only dispose of product residues via authorised companies according to local legislation.

European waste catalogue

Notes: The European Waste Catalogue (EWC) classifies waste materials and categorises them according to what they are and how they were produced. This may cause other classifications. The final decision belongs to the last user.

16 03 05*	organic wastes containing hazardous substances
16 05 08*	discarded organic chemicals consisting of or containing hazardous substances
HP6	Acute Toxicity

Uncleaned packaging:**Recommendation:**

Dispose of packaging according to regulations on the disposal of packagings.

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

SECTION 14: Transport information**14.1 UN number or ID number****ADR/RID/ADN, ADN, IMDG, IATA**

not regulated

14.2 UN proper shipping name**ADR/RID/ADN, ADN, IMDG, IATA**

not regulated

14.3 Transport hazard class(es)**ADR/RID/ADN, ADN, IMDG, IATA****Class**

not regulated

14.4 Packing group**ADR/RID/ADN, IMDG, IATA**

not regulated

14.5 Environmental hazards:

Not applicable.

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14.6 Special precautions for user	Not applicable.
14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
UN "Model Regulation":	not regulated

SECTION 15: Regulatory information

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

National regulations:

Information about limitation of use: Employment restrictions concerning juveniles must be observed.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

Relevant phrases

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

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Training hints

Before handling, storage or use for the first time, employees must be informed about the properties of the substance and about measures taken to ensure safety and environmental protection.

Classification according to Regulation (EC) No 1272/2008

Serious eye damage/irritation Skin sensitisation	The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.
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Department issuing SDS:

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Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

ATE: Acute toxicity estimate values

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 3: Acute toxicity – Category 3

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

*** Data compared to the previous version altered.**