Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)
Product Name: Bilirubin Total, Jendrassik Grof, Reagent 1
Version: 07
Date: March 25, 2024

www.dialab.at

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product Identifier

Bilirubin Total, Jendrassik Grof, Reagent 1

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

Relevant identified use
Reagent for in-vitro diagnostics in human samples
For professional use only

Uses advised against
None

1.3. Details of the supplier of the safety data sheet

Dialab Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H
Hondastrasse, Objekt M55, IZ-NOE Sued, 2351 Wr. Neudorf, Austria

Phone / e-mail: +43 2236 660 910 0 / office@dialab.at

Responsible person:
e-mail: safety@dialab.at

1.4. Emergency telephone number

+43 1 406 43 43 (Gesundheit Österreich GmbH, 24 h)

Section 2. Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) 1272/2008 (CLP):
Skin Corr. 1 H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.

2.2. Label elements

Regulation (EC) 1272/2008 (CLP):

Pictogram(s) and signal words:

GHS05

Signal word: **Danger**

Hazard-determining components of labelling:

Hazard statements:

H314	Causes severe skin burns and eye damage.

Precautionary statements:

P260	Do not breathe dusts or mists.
P280	Wear protective gloves / eye protection / face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Special labelling:

EUH208	Contains sulphanilic acid. May produce an allergic reaction.

2.3. Other hazards

The mixture shall not contain substances listed in accordance with Article 59(1) R.E.A.C.H as having endocrine disrupting properties, or be recognised 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 in a concentration equal to or greater than 0.1%.

Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.

Endocrine disrupting properties:
No further information available.

Section 3. Composition / information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

Chemical characterisation: Mixture.

Hazardous ingredients:

Dimethyl Sulfoxide (DMSO), EC No.: 200-664-3, CAS No.: 67-68-5, REACH No.: 01-2119431362-50-XXXX, RTECS: PV 6210000
Concentration (%): 50 - 100%
Substance with a Community workplace exposure limit.

Ethanediol, EC No.: 203-473-3, CAS No.: 107-21-1, Index No.: 603-027-00-1, REACH No.: 01-2119456816-28, RTECS: KW 2975000
Concentration (%): 10 – 25%
Classification according to Regulation (EC) 1272/2008: Acute Tox. 4, H302.

Sulphanilic acid, EC No.: 204-482-5, CAS No.: 121-57-3, Index No.: 612-014-00-X, RTECS: WP 3895500
Concentration (%): < 1 %
Classification according to Regulation (EC) 1272/2008: Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317.

Components with occupational exposure limits:
Dimethyl Sulfoxide (DMSO), EC No.: 200-664-3, CAS No.: 67-68-5, REACH No.: 01-2119431362-50-XXXX, RTECS: PV 6210000

Ethanediol, EC No.: 203-473-3, CAS No.: 107-21-1, Index No.: 603-027-00-1, REACH No.: 01-2119456816-28, RTECS: KW 2975000

The wording of the listed hazard warnings can be found in Section 16.

Substances that are on the "Candidate List of Substances of Very High Concern (SVHC) for authorization by the European Chemicals Agency (ECHA) are not intended to be part of this product. It is therefore not to be expected that these substances are contained in the product in quantities of > 0.1 %.

Section 4. First aid measures

4.1. Description of first aid measures

General information:
Immediately remove any clothing soiled by the product.

Following inhalation:
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient in a stable laying down side position for transportation.

Following skin contact:
Immediately wash with water and soap and rinse thoroughly.

Following eye contact:
Rinse opened eye for several minutes under running water. Then consult a doctor.

Following ingestion:
Do not induce vomiting; call for medical help immediately.
Drink plenty of water and provide fresh air. Call for a doctor immediately.

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

No further relevant information is available.

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

No further relevant information is available.

Section 5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:
Use fire extinguishing methods suitable to surrounding conditions.

Unsuitable extinguishing media:
No data available.

5.2. Special hazards arising from the substance or mixture

No further relevant information available.

5.3. Advice for firefighters

Special protective equipment for firefighters:
No special measures required.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

For non-emergency personnel:
No other relevant information available.

For emergency responders:
No other relevant information available.

6.2. Environmental precautions

Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Dilute with plenty of water.
Do not allow the product to enter sewers/ surface water or ground water.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralising agent.
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.

6.4. Reference to other sections

See Section 7 for information on safe handling.
See Section 8 for information on personal protective equipment.
See Section 13 for disposal information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Avoid contact with eyes, skin and clothing.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.

Information about fire - and explosion protection: No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Protect from frost.

Hints on joint storage: Store away from flammable substances.
Store away from oxidising agents.
Store and load away from food and drink, including animal feed.

Storage class: 8B = Non-combustible corrosive substances.

7.3. Specific end use(s):

No information available.

Section 8. Exposure controls/personal protection

8.1. Control parameters

Ingredients with limit values that require monitoring at the workplace:

Dimethyl Sulfoxide (DMSO), CAS No.: 67-68-5

Type	Limit value
Austria: MAK, TMW, H	160 mg/m³, 50 ppm
Switzerland: MAK short-term, H	320 mg/m³, 100 ppm
Switzerland: MAK long-term, H	160 mg/m³, 50 ppm

Ethanediol, CAS No.: 107-21-1

Type	Limit value
Austria: MAK, TMW, H	26 mg/m³, 10 ppm
Austria: MAK, KZW, H	52 mg/m³, 20 ppm
Europe: IOELV, short-term, Skin	104 mg/m³, 40 ppm
Europe: IOELV, long-term, Skin	52 mg/m³, 20 ppm
Great Britain: WEL short-term, Sk	104** mg/m³, 40** ppm (** vapour)
Great Britain: WEL long-term, Sk	10* 52** mg/m³, 20** ppm (*particulate, **vapour)
Switzerland: MAK short-term, H SSc	52 mg/m³, 20 ppm
Switzerland: MAK long-term, H SSc	26 mg/m³, 10 ppm

DNELs

Dimethyl Sulfoxide (DMSO), CAS No.: 67-68-5

Oral	DNEL Public long-term systemic	100 mg/kg bw/d
Dermal	DNEL Public long-term systemic	200 mg/kg bw/d
	DNEL Worker long-term systemic	400 mg/kg bw/d
Inhalative	DNEL Public long-term systemic	70 mg/m³
	DNEL Worker long-term systemic	394 mg/m³

PNECs

Dimethyl Sulfoxide (DMSO), CAS No.: 67-68-5

PNEC STP	11 mg/L
PNEC aqua (fresh water)	17 mg/L
PNEC aqua (marine water)	1.7 mg/L
PNEC sediment (fresh water)	55.75 mg/kg
PNEC soil	3.02 mg/kg

Additional information:
The most current valid lists have been used as a basis for the production of this document.

8.2. Exposure controls

Appropriate engineering controls
No further data; see section 7.

Individual protection measures, such as personal protective equipment

Respiratory protection: No special measures required.

Hand protection:

Protective gloves according to EN 374.
Glove material: Butyl rubber, BR – Breakthrough time: > 480 min
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye/face protection:

Tightly sealed goggles according to EN 166.

Body protection:

Protective work clothing.

General protection and hygiene measures:
Keep away from food, beverages and petfood.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.

Environmental exposure controls
Refer to "6.2 Environmental precautions".

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties:

General information	
Physical State	At 20 °C and 101.3 kPa: liquid
Colour	Colourless to pale yellow
Odour	Solvent odour
Odour threhold	No data available
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability	Not applicable
Lower and upper explosion limit	No data available
Flash point	Not applicable
Auto-ignition temperature	Not applicable
Decomposition temperature	No data available
pH	At 25 °C: < 2
Kinematic viscosity	No data available
Dynamic	No data available

Solubility in water / in other solvents	Water: completely miscible
Partition coefficient n-octanol/water (log value)	No data available
Vapour pressure	No data available
Density	At 20°C: 1.0750 g/mL
Relative density	No data available
Vapour density	No data available

9.2. Other information

Information with regard to physical hazard classes:

Explosives	Not classified as hazardous.
Flammable gases	Not classified as hazardous.
Aerosols	Not classified as hazardous.
Oxidising gases	Not classified as hazardous.
Gases under pressure	Not classified as hazardous.
Flammable liquids	Not classified as hazardous.
Flammable solids	Not classified as hazardous.
Self-reactive substances and mixtures	Not classified as hazardous.
Pyrophoric liquids	Not classified as hazardous.
Pyrophoric solids	Not classified as hazardous.
Self-heating substances and mixtures	Not classified as hazardous.
Substances and mixtures, which emit flammable gases in contact with water	Not classified as hazardous.
Oxidising liquids	Not classified as hazardous.
Oxidising solids	Not classified as hazardous.
Organic peroxides	Not classified as hazardous.
Corrosive to metals	Not classified as hazardous.
Desensitised explosives	Not classified as hazardous.

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

Ignition temperature	Product is not self-igniting.
Explosive properties	Product does not present an explosion hazard.
Change in condition:	
Evaporation rate	Not determined.

Section 10. Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Thermal decomposition / conditions to be avoided:
No decomposition if used according to specifications.

10.3. Possibility of hazardous reactions

Reacts with strong alkali.

10.4. Conditions to avoid

No further relevant information available.

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

Toxicological effects:

Acute toxicity (oral): Based on available data, the classification criteria are not met.

Acute toxicity (dermal): Based on available data, the classification criteria are not met.

Acute toxicity (inhalative): Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:

Dimethyl Sulfoxide (DMSO), CAS No.: 67-68-5
Oral LD50 14500 mg/kg (rat)

Ethanediol, CAS No.: 107-21-1
Oral LD50 5840 mg/kg (rat)
Dermal LD50 9530 mg/kg (rabbit)

Sulphanilic acid, CAS No.: 121-57-3
Oral LD50 12300 mg/kg (rat)

Skin corrosion/irritation: Causes severe skin burns and eye damage.

Serious eye damage / irritation: Causes serious eye damage.

Sensitisation to the respiratory tract: Based on available data, the classification criteria are not met.

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

Germ cell mutagenicity/Genotoxicity: 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.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Based on available data, the classification criteria are not met.

Specific target organ toxicity (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:

Dimethyl Sulfoxide (DMSO), CAS No.: 67-68-5
EC50 72h 17000 mg/L (Algae)
EC50 48h 24600 mg/L (daphnia)
33500 mg/L (fish)
EC50 96h >2500 mg/L (fish)

Ethanediol, CAS No.: 107-21-1
LC50 96h 41000 mg/L (*Oncorhynchus mykiss*)
EC50 48h 46300 mg/L (daphnia)

Water Hazard Class: 1 = slightly hazardous to water.

12.2. Persistence and degradability

Further details: No data available.

12.3. Bioaccumulative potential

Partition coefficient:
n-octanol/water: No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Not applicable.

12.6. Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

12.7. Other adverse effects

No further relevant information available.

Additional ecological information:

General information: Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
Thowing away bigger amounts into drains or aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the diluted product use, the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only slightly polluting for water.

Section 13. Disposal considerations

13.1. Waste treatment methods

Recommendation:

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

Uncleaned packaging:
Recommendation: Disposal must be made according to official regulations.
Recommended cleansing agents: Water, if necessary together with cleansing agents.

Section 14. Transport information

14.1. UN number or ID number

DOT, ADR, IMDG, IATA: UN3264.

14.2. UN proper shipping name

ADR: UN3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S.

IMDG, IATA: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S.

14.3. Transport hazard class(es)

ADR: Class: 8 (C1) Corrosive substances
Label: 8

IMDG, IATA: Class: 8, Corrosive substances
Label: 8

14.4. Packing group

ADR, IMDG, IATA: III

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Warning: Corrosive substances.

Hazard identification number (Kemler code):	80
EMS Number:	F-A, S-B
Segregation groups:	(SGG1) Acids
Stowage Category	A
Stowage Code	SW2 Clear of living quarters
Segregation Code	SG36 Stow "separated from" SGG18-alkalis SG49 Stow "separated from" SGG6-cyanides

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

Transport/Additional information:

Quantity limitations	On passenger aircraft/rail: 5 L On cargo aircraft only: 60 L

ADR

Limited quantities (LQ):	5L
Excepted quantities (EQ):	Code: E1 Maximum net quantity per inner packaging: 30 mL Maximum net quantity per outer packaging: 1000 mL
Transport category:	3
Tunnel restriction code:	E

IMDG

Limited quantities (LQ):	5L
Excepted quantities (EQ):	Code: E1 Maximum net quantity per inner packaging: 30 mL Maximum net quantity per outer packaging: 1000 mL
UN "Model Regulation":	UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. 8, III

Section 15. Regulatory information

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

Poisons Act
Regulated explosives precursors
None of the ingredients is listed.

Regulated poisons
None of the ingredients is listed.

Reportable explosives precursors
None of the ingredients is listed.

Reportable poisons
None of the ingredients is listed.

Directive 2012/18/EU
Named dangerous substances - Annex I
None of the ingredients is listed.

Regulation (EC) No 1907/2006 - Annex XVII
Conditions of restriction: 3

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- Repotable 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 – Austria:
Storage class: 8B = Non-combustible corrosive substances.

National regulations – France:
No data available.

National regulations – Germany:
Storage class: 8B = Non-combustible corrosive substances.

Water hazard class: 1 = slightly hazardous to water.

Technical instructions (air):

Class	Share in %
Water	25-<50
NK	50-100

Further regulations, limitations and legal requirements: No data available.

National regulations – Switzerland:
No data available.

15.2. Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

Section 16. Other information

Reason of Change:
Implementation of updated requirements for the compilation of SDS according to COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Hazard statements mentioned in Sections 2 and 3:
Directive (EC) 127/2008:
H302 = Harmful if swallowed.
H314 = Causes severe skin burns and eye damage.
H315 = Causes skin irritation.
H317 = May cause an allergic skin reaction.
H318 = Causes serious eye damage.
H319 = Causes serious eye irritation.

Classification according to Regulation (EC) No 1272/2008

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

Abbreviations and acronyms:
Acute Tox. 4: Acute toxicity – Category 4
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS: Chemical Abstracts Service
CLP: Classification, Labelling and Packaging
DOT: US Department of Transportation
DNEL: Derived No-Effect Level

EC: European Community
EC50: Effective Concentration 50%
EN: European Standard
EU: European Union
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
IATA: International Air Transport Association
IMDG: International Maritime Dangerous Goods
IMO: International Maritime Organization
IOEL: Indicative Occupational Exposure Limit Value
KZW: Kurzzeitwert
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
MAK: Maximale Arbeitsplatz-Konzentration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted No-Effect Concentration
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
Skin Corr. 1: Skin corrosion/irritation – Category 1
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
TMW: Tagesmittelwert
UN: United Nations
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

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