

Safety Data Sheet

according to Regulation (EU) 2020/878 Issue date: 15.06.2023 Version: 1.0

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

1.1. Product identifier	
Product form Trade name	<ul> <li>Mixture</li> <li>Mobile Phase 1, Premier Resolution Mobile Phase 1, Menarini Resolution Mobile Phase 1, GeneSys 1, Mobile Phase 2, Premier Resolution Mobile Phase 2, Menarini Resolution Mobile Phase 2, GeneSys 2</li> <li>Mobile Phase 2, GeneSys 2</li> </ul>
Other means of identification	<ul> <li>01-03-0040 Mobile Phase 1, 3.8L, 01-03-0042 Mobile Phase 1, 940mL,</li> <li>01-03-0084 Premier Resolution Mobile Phase 1, 3.8L, 01-03-0082 Premier Resolution Mobile Phase 1, 940mL,</li> <li>45713 Menarini Resolution Mobile Phase 1, 3.8L, 50033 Menarini Resolution Mobile Phase 1, 940mL,</li> <li>01-03-0020 GeneSys 1, 3.8L, 01-03-0022 GeneSys 2, 3.8L,</li> <li>01-03-0020 GeneSys 1, 3.8L, 01-03-0044 Mobile Phase 2, 940mL,</li> <li>01-03-0041 Mobile Phase 2, 3.8L, 01-03-0044 Mobile Phase 2, 940mL,</li> <li>01-03-0085 Premier Resolution Mobile Phase 2, 3.8L, 01-03-0083 Premier Resolution Mobile Phase 2, 940mL,</li> <li>45714 Menarini Resolution Mobile Phase 2, 3.8L, 50034 Menarini Resolution Mobile Phase 2, 940mL</li> </ul>
1.2. Relevant identified uses of the substan	ce or mixture and uses advised against
1.2.1. Relevant identified uses	
Use of the substance/mixture	: Medical device
1.2.2. Uses advised against	
Restrictions on use	: No additional information available
1.3. Details of the supplier of the safety data	a sheet
Manufacturer Trinity Biotech 4231 E. 75th Terrace Kansas City, MO 64132 USA	Authorized representative Trinity Biotech I.D.A Business Park Southern Cross Road A98 H5C8 Bray, Co. Wicklow - Ireland Technical Support Group 00353 1 276 9800 www.trinitybiotech.com haemoglobins.techsupport@trinitybiotech.com
1.4. Emergency telephone number	
Emergency number	: Contact your local Emergency Health Care Provider; Ireland-Technical Support Group 00353-1-276-9800 (operating hours 7:00-18:00)

SECTION 2: Hazards identification	า
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2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

## Safety Data Sheet

according to Regulation (EU) 2020/878

## 2.2. Label elements

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

No labelling applicable

#### 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 %

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

### 3.1. Substances

### Not applicable

#### 3.2. Mixtures

Name	Product identifier	Conc.	Classification according to Regulation (EC) No. 1272/2008 [CLP]
potassium cyanide (Note A)	CAS-No.: 151-50-8 EC-No.: 205-792-3 EC Index-No.: 006-007-00-5	< 0.015	Met. Corr. 1, H290 Acute Tox. 1 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 STOT RE 1, H372 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)

Note A: Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3. In Part 3, use is sometimes made of a general description such as 'compounds' or 'salts'. In this case, the supplier is required to state on the label the correct name, due account being taken of section 1.1.1.4.

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	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.
First-aid measures after inhalation	: If inhaled and if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If you feel unwell, seek medical advice.
First-aid measures after skin contact	<ul> <li>Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Get medical attention if symptoms occur. Wash contaminated clothing before reuse.</li> </ul>
First-aid measures after eye contact	<ul> <li>Immediately rinse with water for a prolonged period while holding the eyelids wide open.</li> <li>Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if you feel unwell.</li> </ul>
First-aid measures after ingestion	: Do NOT induce vomiting unless directed to do so by medical personnel. Rinse mouth out with water. Get medical advice/attention if you feel unwell.

## Safety Data Sheet

according to Regulation (EU) 2020/878

4.2. Most important symptoms and effe	cts, both acute and delayed
Symptoms/effects after inhalation	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/effects after skin contact	: Not expected to present a significant skin hazard under anticipated conditions of normal use.
Symptoms/effects after eye contact	: Not expected to present a significant eye contact hazard under anticipated conditions of normal use.
Symptoms/effects after ingestion	: Not expected to present a significant hazard under anticipated conditions of normal use.
4.3. Indication of any immediate medica	al attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures	
5.1. Extinguishing media	
Suitable extinguishing media Unsuitable extinguishing media	<ul> <li>Dry chemical, CO2, or water spray or regular foam. Use extinguishing agent suitable for surrounding fire.</li> <li>Do not use a heavy water stream.</li> </ul>
5.2. Special hazards arising from the subst	tance or mixture
Fire hazard Hazardous decomposition products in case of fire	<ul> <li>Presents no particular fire or explosion hazard. Burning produces stinking and toxic fumes.</li> <li>In case of fire and/or explosion do not breathe fumes.</li> <li>Toxic fumes may be released.</li> </ul>
5.3. Advice for firefighters	
Firefighting instructions Protection during firefighting	<ul> <li>Evacuate the danger area. Fight fire from safe distance and protected location. Move containers from fire area if it can be done without personal risk. Use extinguishing media appropriate for surrounding fire. Use water spray or fog for cooling exposed containers. Prevent fire fighting water from entering the environment.</li> <li>Wear a self contained breathing apparatus. Wear fire/flame resistant/retardant clothing. Do not attempt to take action without suitable protective equipment.</li> </ul>

6.1. Personal precautions, protective equipment and emergency procedures		
6.1.1. For non-emergency personnel		
Protective equipment Emergency procedures	<ul> <li>Wear recommended personal protective equipment. Refer to section 8.2.</li> <li>No action shall be taken without appropriate training or involving any personal risk. Do not touch or walk on the spilled product. Evacuate unnecessary personnel. Ventilate spillage area. Avoid contact with skin and eyes.</li> </ul>	
6.1.2. For emergency responders		
Protective equipment Emergency procedures	<ul> <li>Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".</li> <li>Stop leak if safe to do so. Ventilate area. Do not touch spilled material.</li> </ul>	
6.2. Environmental precautions		
0.2. Environmental precautions		

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

## Safety Data Sheet

according to Regulation (EU) 2020/878

	tainment and cleaning up
For containment	: Stop leak without risks if possible. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Caution : this product can cause the floor to be slippery.
Methods for cleaning up	: Move containers from spill area. Ventilate spillage area. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Clean contaminated surfaces with an excess of water. Keep in suitable, closed containers for disposal.
Other information	<ul> <li>Dispose of via an authorised person/ licensed waste disposal contractor or by other suitable waste treatment techniques. Dispose of materials or solid residues at an authorized site.</li> </ul>

For further information refer to section 13. For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: Handling and storage	
7.1. Precautions for safe handling	
Precautions for safe handling Hygiene measures	<ul> <li>Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Ensure good ventilation of the work station. Provide local exhaust or general room ventilation. Do not breathe vapours, mist. Do not get in eyes, on skin, or on clothing. Wear personal protective equipment. Obtain special instructions before use.</li> <li>Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Wash contaminated clothing before reuse.</li> </ul>
7.2. Conditions for safe storage, including a	ny incompatibilities
Storage conditions	: Keep only in the original container in a cool, well ventilated place away from : Direct sunlight, Incompatible materials, Protect from freezing, Avoid high temperatures. Keep away from food, drink and animal feedingstuffs. Keep container tightly closed. Containers which are opened should be properly resealed and kept upright to prevent leakage. Store in accordance with local, regional, national or international regulation.

## 7.3. Specific end use(s)

No additional information available

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

#### 8.1. Control parameters

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

potassium cyanide (151-50-8)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Potassium cyanide (as cyanide)
IOEL TWA	1 mg/m³
IOEL STEL	5 mg/m³
Remark	Skin
Regulatory reference	COMMISSION DIRECTIVE (EU) 2017/164

## Safety Data Sheet

according to Regulation (EU) 2020/878

potassium cyanide (151-50-8)	
Ireland - Occupational Exposure Limits	
Local name	Potassium cyanide (as cyanide)
OEL TWA [1]	1 mg/m <sup>3</sup>
OEL STEL	5 mg/m³
Remark	IOELV (Indicative Occupational Exposure Limit Values), Sk (Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body)
Regulatory reference	Chemical Agents Code of Practice 2021

#### 8.1.2. Recommended monitoring procedures

Monitoring methods	
Monitoring methods	Refer to all applicable national, international and local regulations or provisions. Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents. Workplace atmospheres. Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy. Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

#### 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:

Handle in accordance with good industrial hygiene and safety procedures. Ensure good ventilation of the work station. Avoid all unnecessary exposure.

#### 8.2.2. Personal protection equipment

#### Personal protective equipment:

Wear recommended personal protective equipment. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

#### 8.2.2.1. Eye and face protection

#### Eye protection:

Even though no specific eye irritation data are available, wear eye protection appropriate to conditions of use when handling this material. ISO 16321-1

#### 8.2.2.2. Skin protection

#### Skin and body protection:

Wear suitable protective clothing. Skin protection appropriate to the conditions of use should be provided

## Hand protection:

Chemical resistant gloves (according to European standard ISO 374-1 or equivalent). Please follow the instructions related to the permeability and the penetration time provided by the manufacturer

## Safety Data Sheet according to Regulation (EU) 2020/878

#### 8.2.2.3. Respiratory protection

#### **Respiratory protection:**

No respiratory protection needed under normal use conditions. Where excessive vapour, mist, or dust may result, use approved respiratory protection equipment. EN 149

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment. Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil.

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

## 9.1. Information on basic physical and chemical properties

Physical state Colour	: Liquid : According to product specification.
Odour	: According to product specification.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
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	: Not available
Relative density	: Not available
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

## SECTION 10: Stability and reactivity

#### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport. No dangerous reactions known.

### **10.2. Chemical stability**

Stable under normal conditions.

## Safety Data Sheet

according to Regulation (EU) 2020/878

10.3. Possibility of hazardous reactions

Hazardous polymerisation: Will not occur. 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

Strong bases. Strong acids. Strong oxidizing agents. Strong reducing agents.

**10.6. Hazardous decomposition products** 

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11.1. Information on hazard classes as o	lefined in Regulation (EC) No 1272/2008
Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation)	<ul> <li>Not classified (Based on available data, the classification criteria are not met)</li> <li>Not classified (Based on available data, the classification criteria are not met)</li> <li>Not classified (Based on available data, the classification criteria are not met)</li> </ul>
potassium cyanide (151-50-8)	
LD50 oral	0,51 mg/kg Expert judgement
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
potassium cyanide (151-50-8)	
STOT-repeated exposure	Causes damage to organs (thyroid gland) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)
11.2. Information on other hazards	
11.2.1. Endocrine disrupting properties	
Adverse health effects caused by endocrine disrupting properties	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 %

11.2.2. Other information

Other information

: No experimental study on the product is available. The information given is based on our knowledge of the components and the classification of the product is determined by calculation

## Safety Data Sheet

according to Regulation (EU) 2020/878

SECTION 12: Ecological information	
12.1. Toxicity	
Hazardous to the aquatic environment, short-term : (acute)	Not classified (Based on available data, the classification criteria are not met)
	Not classified (Based on available data, the classification criteria are not met)
	No experimental study on the product is available. The information given is based on our knowledge of the components and the classification of the product is determined by calculation.
potassium cyanide (151-50-8)	
EC50 - Crustacea [1]	0,0709 mg/l (96 h, ECHA, flow-through test)
12.2. Persistence and degradability	
Mobile Phase 1, Premier Resolution Mobile F Premier Resolution Mobile Phase 2, Menarin	Phase 1, Menarini Resolution Mobile Phase 1, GeneSys 1, Mobile Phase 2, i Resolution Mobile Phase 2, GeneSys 2
Persistence and degradability	Biodegradability in water: no data available.
12.3. Bioaccumulative potential	
Mobile Phase 1, Premier Resolution Mobile F Premier Resolution Mobile Phase 2, Menarin	Phase 1, Menarini Resolution Mobile Phase 1, GeneSys 1, Mobile Phase 2, i Resolution Mobile Phase 2, GeneSys 2
Bioaccumulative potential	No data available concerning bioaccumulation.
12.4. Mobility in soil	
Mobile Phase 1, Premier Resolution Mobile F Premier Resolution Mobile Phase 2, Menarin	Phase 1, Menarini Resolution Mobile Phase 1, GeneSys 1, Mobile Phase 2, i Resolution Mobile Phase 2, GeneSys 2
Ecology - soil	No additional information available.
12.5. Results of PBT and vPvB assessment	
No additional information available	
12.6. Endocrine disrupting properties	
Adverse effects on the environment caused by endocrine disrupting properties	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 %.
12.7. Other adverse effects	
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.

#### Waste treatment methods

Disposal must be carried out using appropriate EWC code. Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Safety Data Sheet

according to Regulation (EU) 2020/878

Ecology - waste materials

: Avoid release to the environment.

## **SECTION 14: Transport information**

n accordance with ADR / IMDG / IATA / ADN / RID				
ADR	IMDG	ΙΑΤΑ	ADN	RID
14.1. UN number or ID n	umber			
Not regulated for transport				
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	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 haz	ards			
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information	on 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. 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

#### **REACH Annex XVII (Restriction List)**

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

## Safety Data Sheet according to Regulation (EU) 2020/878

#### **REACH Annex XIV (Authorisation List)**

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

#### **REACH Candidate List (SVHC)**

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

#### **PIC Regulation (Prior Informed Consent)**

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

## POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

#### **Explosives Precursors Regulation (2019/1148)**

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

#### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 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**

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
ΙΑΤΑ	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level

## Safety Data Sheet

according to Regulation (EU) 2020/878

Abbreviations and acronyms:	
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
РВТ	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

Data sources

 ECHA (European Chemicals Agency). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 and all its amendments and modifications. Supplier's safety documents.
 Training staff on good practice.

Training advice

Full text of H- and EUH-statements:	
Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 1 (Oral)	Acute toxicity (oral), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
H290	May be corrosive to metals.
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Met. Corr. 1	Corrosive to metals, Category 1
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Safety Data Sheet (SDS), EU

SDS prepared by: H2 Compliance

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.