

SAFETY DATA SHEET

Invivoscribe® BCR/ABL Dilution Sets

Catalog Number	Description	
40850110	BCR/ABL e1a2 RNA Dilution Set	
40850210	BCR/ABL b3a2 RNA Dilution Set	
40850310	BCR/ABL b2a2 RNA Dilution Set	



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 as amended by Commission Regulation (EU) 2020/878 and Regulation (EC) No. 1272/2008

Issuing Date 27-Apr-2023

Revision Date 27-Apr-2023

Revision Number 1

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

1.1. Product identifier

Product Code(s)	Product Name	Synonyms
40840110	BCR/ABL e1a2 Negative RNA	None
40840120	10 ⁻¹ BCR/ABL e1a2 RNA	None
40840130	10 ⁻² BCR/ABL e1a2 RNA	None
40840140	10 ⁻³ BCR/ABL e1a2 RNA	None
40840150	10 ⁻⁴ BCR/ABL e1a2 RNA	None
40840160	10 ⁻⁵ BCR/ABL e1a2 RNA	None
40840210	BCR/ABL b3a2 Negative RNA	None
40840220	10 ⁻¹ BCR/ABL b3a2 RNA	None
40840230	10 ⁻² BCR/ABL b3a2 RNA	None
40840240	10 ⁻³ <i>BCR/ABL</i> b3a2 RNA	None
40840250	10 ⁻⁴ BCR/ABL b3a2 RNA	None
40840260	10 ⁻⁵ <i>BCR/ABL</i> b3a2 RNA	None
40840310	BCR/ABL b2a2 Negative RNA	None
40840320	10 ⁻¹ BCR/ABL b2a2 RNA	None
40840330	10 ⁻² BCR/ABL b2a2 RNA	None
40840340	10 ⁻³ BCR/ABL b2a2 RNA	None
40840350	10 ⁻⁴ BCR/ABL b2a2 RNA	None
40840360	10 ⁻⁵ <i>BCR/ABL</i> b2a2 RNA	None

Pure substance/mixture Mixture

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

Recommended use	Assay reagent
Uses advised against	For professional use only

1.3. Details of the supplier of the safety data sheet

Importer_		
Invivoscribe Technologies		
Zeppelinstrasse 1		
85399 Hallbergmoos		
Germany		
Phone: +49 89 904 299 800		

Supplier Invivoscribe, Inc. 10222 Barnes Canyon Rd Bldg. 1 San Diego, CA 92121 Phone: +1 858-224-6600

Distributor

Invivoscribe Technologies, SARL c/o Ficorec Domiciliation Services 132, Boulevard Michelet Hall Nord – 5ème étage 13008 Marseille FRANCE Tel: +33 (0)4 42 01 78 10

For further information, please contact

E-mail address customerservice@invivoscribe.com

1.4. Emergency telephone number

Emergency telephone	+49 89 904 299 800 (M-F 8:00 – 16:30 CET)		
Emergency telephone	- §45 - (EC)1272/2008		
Europe		112	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

2.2. Label elements

Hazard statementsNot classified.Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

2.3. Other hazards

No information available. Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

Information

3.1 Substances

The product contains no substances which at their given concentration, are considered to be hazardous to health.

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

SECTION 3: Composition/information on ingredients

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation Eye contact	— Remove to fresh air. Get medical attention if symptoms occur. Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact Ingestion	Wash skin with soap and water. Get medical attention if symptoms occur. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth. Get medical attention if symptoms occur.

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

Symptoms	None known.
Effects of Exposure	No information available.

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

Note to physicians Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the
	surrounding environment.
Unsuitable extinguishing media	No information available.

5.2. Special hazards arising from the substance or mixture

SECT	SECTION 5: Firefighting measures			
3201				
	Specific hazards arising from the o	memical No information available.		
<u>5.3.</u>	Advice for firefighters			
	Special protective equipment and			
	precautions for fire-fighters	turnout gear. Use personal protection equipment.		
SECT	ION 6: Accidental release r	neasures		
<u>6.1.</u>	Personal precautions, protective e	quipment and emergency procedures		
	Personal precautions	Ensure adequate ventilation.		
	For emergency responders	Use personal protection recommended in Section 8.		
6.2.	Environmental precautions			
	Environmental precautions	See Section 12 for additional Ecological Information.		
c a	na she de su dou she del ferro su de tu			
<u>6.3.</u>	Methods and material for contain Methods for containment			
	Methods for cleaning up	Prevent further leakage or spillage if safe to do so. Dam up. Soak up with inert absorbent material. Take up mechanically, placing in appropriate		
	methous for cleaning up	containers for disposal.		
	Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.		
6.4.	Reference to other sections			
<u></u>	Reference to other sections	See section 8 for more information See section 13 for more information		
<u>7.1.</u>	Precautions for safe handling			
<u>/.1</u> .	Advice on safe handling	Handle in accordance with good industrial bugiene and cafety practice		
	General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice. Handle in accordance with good industrial hygiene and safety practice.		
<u>7.2.</u>	Conditions for safe storage, includ			
	Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.		
	Storage class (TRGS 510)	Storage class 10.		
7.3.	Specific end use(s)			
	Specific use(s)	The identified uses for this product are detailed in Section 1.2.		
SECT	ION 8: Exposure controls/	personal protection		
8.1.	Control parameters			
<u></u>	Exposure Limits	This product, as supplied, does not contain any hazardous materials with occupational exposure		
	limits established by the region specific regulatory bodies.			
	Biological occupational exposure I			
	This product, as supplied, does not bodies.	contain any hazardous materials with biological limits established by the region-specific regulatory		
	Derived No Effect Level (DNEL) - V	Vorkers No information available.		
	Derived No Effect Level (DNEL) - G			
	Predicted No Effect Concentration			
8.2.	Exposure controls			

SECTION 8: Exposure controls/personal protection

Engineering controls	Showers
	Eyewash stations
	Ventilation systems.
Personal protective equipment	
Eye/face protection	Wear safety glasses with side shields (or goggles). Eye protection must conform to standard EN 166.
Hand protection	Wear suitable gloves. Gloves must conform to standard EN 374.
Skin and body protection	Wear suitable protective clothing. (EN ISO 6529).
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
Environmental exposure controls	No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Liquid
Color	Colorless
Odor	Odorless
Odor threshold	No information available

Property	<u>Values</u>	<u> Remarks • Method</u>
Melting point / freezing point		No data available
Initial boiling point and boiling range		No data available
Flammability		No data available
Flammability Limit in Air		No data available
Upper flammability or explosive limits		No data available
Lower flammability or explosive limits		No data available
Flash point		No data available
Autoignition temperature		No data available
Decomposition temperature		No data available
рН		No data available
pH (as aqueous solution)		No data available
Kinematic viscosity		No data available
Dynamic viscosity		No data available
Water solubility		No data available
Solubility(ies)		No data available
Partition coefficient		No data available
Vapor pressure		No data available
Relative density		No data available
Bulk density		No data available
Liquid density		No data available
Relative vapor density		No data available
Particle characteristics		No data available
Particle size		No data available
Particle size distribution		No data available

9.2. Other information

9.2.1.

. Information with regard to physical hazard classes Not applicable

SECTION 9: Physical and chemical properties

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

<u>10.1.</u>	<u>Reactivity</u> Reactivity	None under normal use conditions.
<u>10.2.</u>	<u>Chemical stability</u> Stability Explosion data	Stable under normal conditions.
	Sensitivity to mechanical impact	None.
	Sensitivity to static discharge	None.
<u>10.3.</u>	Possibility of hazardous reactions Possibility of hazardous reactions	None under normal processing.
<u>10.4.</u>	Conditions to avoid Conditions to avoid	None known based on information supplied.
<u>10.5.</u>	Incompatible materials Incompatible materials	None known based on information supplied.
<u>10.6.</u>	Hazardous decomposition products Hazardous decomposition products	None known based on information supplied.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Product Information				
Inhalation Specific test data for the substance or mixture is not available.				
Eye contact	Specific test data for the substance or mixture is not available. Contact with eyes may cause irritation.			
Skin contact	Specific test data for the substance or mixture is not available.			
Ingestion	Specific test data for the substance or mixture is not available.			

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms None known.

Acute toxicity

Numerical measures of toxicity

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

Component Information

Delayed and immediate effects as well as chronic effects from short and long-term exposure

SECTION 11: Toxicological information			
SECTION 11: Toxicological information			
Skin corr	osion/irritation	Based on available data, the classification criteria are not met.	
Serious e	eye damage/eye irritation	Based on available data, the classification criteria are not met.	
Respirato	ory or skin sensitization	Based on available data, the classification criteria are not met.	
Germ ce	ll mutagenicity	Based on available data, the classification criteria are not met.	
Carcinog	enicity	Based on available data, the classification criteria are not met.	
Reprodu	ctive toxicity	Based on available data, the classification criteria are not met.	
STOT - si	ngle exposure	Based on available data, the classification criteria are not met.	
STOT - re	peated 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 11.2.1. Endocrine disrupting propertie		erties	
11.2.2.	Endocrine disrupting prope Other information	This product does not contain any known or suspected endocrine disruptors.	
	Other adverse effects	No information available.	
SECTION 12: Ecological information			
Ecotoxici	•	sed on available data, the classification criteria are not met. Based on available data, the ssification criteria are not met.	

Contains 0 % of components with unknown hazards to the aquatic environment.

12.5.	Results of PBT and vPvB assessment

Unknown aquatic toxicity

Persistence and degradability

12.2. Persistence and degradability

12.3. Bioaccumulative potential Bioaccumulation

12.4. Mobility in soil Mobility in soil

PBT and vPvB assessment The product does not contain any substance(s) classified as PBT or vPvB.

No information available.

No information available.

No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

12.7. Other adverse effects

Other adverse effects No information available.

SECTION 13: Disposal considerations

<u>13.1.</u>	Waste treatment methods		
	Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.	
	Contaminated packaging	Do not reuse empty containers.	
	Waste codes / waste designations according to EWC / AVV	According to the European Waste Catalog, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.	

SECTION 14: Transport information		
IMDG		Not regulated
14.1	UN number or ID number	Not regulated
14.2	UN proper shipping name	Not regulated
14.3	Transport hazard class(es)	Not regulated
14.4	Packing group	Not applicable
14.5	Environmental hazards	Not applicable
14.6	Special Precautions for Users	
	Special Provisions	None
14.7	Maritime transport in bulk according to IMO instruments	No information available
<u>RID</u>		Not regulated
14.1	UN number	Not regulated
14.2	UN proper shipping name	Not regulated
14.3	Transport hazard class(es)	Not regulated
14.4	Packing group	Not applicable
14.5	Environmental hazards	Not applicable
14.6	Special Precautions for Users	
	Special Provisions	None
<u>ADR</u>		Not regulated
14.1	UN number or ID number	Not regulated
14.2	UN proper shipping name	Not regulated
14.3	Transport hazard class(es)	Not regulated
14.4	Packing group	Not applicable
14.5	Environmental hazards	Not applicable
14.6	Special Precautions for Users	
	Special Provisions	None
IATA		Not regulated
14.1	UN number or ID number	Not regulated
14.2	UN proper shipping name	Not regulated
14.3	Transport hazard class(es)	Not regulated
14.4	Packing group	Not applicable
14.5	Environmental hazards	Not applicable
14.6	Special Precautions for Users	
	Special Provisions	None
	Note:	None

SECTION 15: Regulatory information

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

National regulations	
Germany	
Water hazard class (WGK)	non-hazardous to water (nwg)

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

SECTION 15: Regulatory information			
Authorizations and/or restrictions on use: This product does not contain substances subject to authorization (Re does not contain substances subject to restriction (Regulation (EC) No Persistent Organic Pollutants Not applicable Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable International Inventories Contact supplier for inventory compliance status			
15.2. Chemical safety assessment Chemical Safety Report No information available			
SECTION 16: Other information			
Key or legend to abbreviations and acronyms used in the safety data sheetLegendATE:ACUTESVHC:Substances of Very High Concern for Authorization:PBT:Persistent, Bioaccumulative, and Toxic (PBT) SubstancesvPvB:Very Persistent and very Bioaccumulative (vPvB) Substances			
Legend Section 8: Exposure controls/personal protection			
TWA TWA (time-weighted average) STE	L STEL (Short Term Exposure Limit)		
Ceiling Maximum limit value *	Skin designation		
SCBA Self-contained breathing apparatus			
Classification procedure			
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used		
Acute oral toxicity	Calculation method		
Acute dermal toxicity	Calculation method		
Acute inhalation toxicity - gas	Calculation method		
Acute inhalation toxicity - vapor	Calculation method		
Acute inhalation toxicity - dust/mist	Calculation method		
Skin corrosion/irritation	Calculation method		
Serious eye damage/eye irritation	Calculation method		
Respiratory sensitization	Calculation method		
Skin sensitization	Calculation method		
Mutagenicity	Calculation method		
Carcinogenicity	On basis of test data		
Reproductive toxicity	Calculation method		
STOT - single exposure	Calculation method		
STOT - repeated exposure	Calculation method		
Acute aquatic toxicity	Calculation method		
Chronic aquatic toxicity	Calculation method		
Aspiration hazard	Calculation method		
Ozone	Calculation method		

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

SECTION 16: Other information

U.S. Environmental Protection Agency Chem	View Database
European Food Safety Authority (EFSA)	
European Chemicals Agency (ECHA) Committ	tee for Risk Assessment (ECHA_RAC)
European Chemicals Agency (ECHA) (ECHA_A	API)
EPA (Environmental Protection Agency)	
Acute Exposure Guideline Level(s) (AEGL(s))	
U.S. Environmental Protection Agency Federa	al Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High P	Production Volume Chemicals
Food Research Journal	
Hazardous Substance Database	
International Uniform Chemical Information	Database (IUCLID)
Japan GHS Classification	
Australia National Industrial Chemicals Notifi	cation and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Sa	afety and Health)
National Library of Medicine's ChemID Plus (I	NLM CIP)
National Library of Medicine's PubMed datab	pase (NLM PUBMED)
United States of America National Toxicology	y Program (NTP)
New Zealand's Chemical Classification and In	formation Database (CCID)
Organization for Economic Co-operation and	Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and	Development High Production Volume Chemicals Program
Organization for Economic Co-operation and	Development Screening Information Data Set
World Health Organization	
Issuing Date 2	27-Apr-2023

Issuing Date	27-Apr-2023
Revision Date	27-Apr-2023
Revision Note	Initial Release.

This safety data sheet complies with the requirements of Commission Regulation (EU) 2020/878 of 18 June 2020 amending Regulation (EC) No. 1907/2006

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet