

Release Date: 4/27/23

REF GTIN	Product Name
01H73-01 00380740001117	CELL-DYN Sapphire and CELL-DYN Ruby Systems
Components:	
01Н73	CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ SHEATH



Page 1/12

Safety Data Sheet

according to 1907/2006/EC, Article 31

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Release date 27.04.2023 Version number 27 (replaces version 26)

Last alteration on 27.04.2023

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

1.1 Product identifier

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ **SHEATH**

· Article number: 01H73

- 1.2 Relevant identified uses of the substance or mixture and uses advised against
 - · Product category PC0 Other
 - · Application of the substance / the preparation: For In Vitro Diagnostic Use
- 1.3 Details of the supplier of the safety data sheet
 - · Supplier:

Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden Tel.: (+49)-6122-58-0

MSDS-Support@Abbott.com

1.4 Emergency telephone number

(+49)-6122-58-0 (English only)

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.

- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.
- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.
- Telephone 09 8010034 if you are calling from New Zealand.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The classification is in alignment with current European regulations. It incorporates information from technical literature and information provided by supplier companies.

· Classification according to Regulation (EC) No 1272/2008:

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

2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008:

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

(Continued on page 2)



Page 2/12

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories

Release date 27.04.2023 Version number 27 (replaces version 26)

Last alteration on 27.04.2023

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ **SHEATH**

(Continued from page 1)

· Hazard pictograms:



· Signal word: Warning

· Hazard-determining components of labelling:

2-Methyl-4-isothiazolin-3-one

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)

· Hazard statements:

H317 May cause an allergic skin reaction.

· Precautionary statements:

Avoid breathing mist / vapours / spray. P261

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves / protective clothing / eye protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention. P362+P364 Take off contaminated clothing and wash it before reuse.

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

· Routes of Exposure: Skin

2.3 Other hazards

· Results of PBT and vPvB assessment:

· **PBT:** Not applicable · vPvB: Not applicable

(Continued on page 3)



Page 3/12

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories

Release date 27.04.2023 Version number 27 (replaces version 26)

Last alteration on 27.04.2023

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ **SHEATH**

(Continued from page 2)

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Dangerous components according to EC criteria:			
CAS: 2682-20-4	2-Methyl-4-isothiazolin-3-one	0.004%	
EINECS: 220-239-6 Reg.nr.: 01-2120764690-50-xxxx	Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 2, H330; Skin Corr. 1B, H314; Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1); Skin Sens. 1, H317		
	Specific concentration limit: Skin Sens. 1A; H317: C ≥ 0.0015 %		
CAS: 55965-84-9 Reg.nr.: 01-2120764691-48-xxx	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3: 1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3: 1)	0.0017%	
	Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 1, H330; Skin Corr. 1C, H314; Eye Dam. 1, H318; Aquatic Acute 1, H400 (M=100); Aquatic Chronic 1, H410 (M=100); Skin Sens. 1A, H317, EUH071 Specific concentration limits: Skin Corr. 1C; H314: $C \ge 0.6$ %		
	Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 % Eye Dam. 1; H318: C ≥ 0.6 % Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 % Skin Sens. 1A; H317: C ≥ 0.0015 %		

· Additional information:

For the complete text of Hazard (H) codes displayed in this section, refer to Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- · General information: Immediately remove any clothing soiled by the product.
- · After inhalation:

Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.

· After skin contact:

Take off any clothing that the product touched. Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.

· After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.

· After swallowing: Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.

(Continued on page 4)



Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories Release date 27.04.2023 Version number 27 (replaces version 26)

Last alteration on 27.04.2023

Page 4/12

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ SHEATH

(Continued from page 3)

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

Allergic reactions

Possibly immune response

This product may cause skin sensitization reactions in some people. See Section 11 for additional information.

• 4.3 Indication of any immediate medical attention and special treatment needed: No additional relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

Dry chemical, carbon dioxide (CO2), water spray or regular foam.

- Caution: CO2 will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
- For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.

5.2 Special hazards arising from the substance or mixture

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

No further relevant information available.

5.3 Advice for firefighters

Protective equipment:

For large fires, wear appropriate heat- and flame-resistant personal protective equipment and an approved positive-pressure, self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

6.2 Environmental precautions

Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

6.3 Methods and material for containment and cleaning up

Blot up small volumes of spilled or spattered product with paper towels or similar materials.

- Contain larger spills by placing absorbants around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

(Continued on page 5)



Page 5/12

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories

Release date 27.04.2023 Version number 27 (replaces version 26)

Last alteration on 27.04.2023

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ **SHEATH**

(Continued from page 4)

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling: Avoid contact with skin.
 - · Information about protection against explosions and fires: No special measures required.
- 7.2 Conditions for safe storage, including any incompatibilities
 - · Storage:
 - Requirements to be met by storerooms and containers: Store only in the original container.
 - Information about storage in one common storage facility: Store in original packaging.
 - · Further information about storage conditions: Refer to the package insert or product label for additional information on storage conditions for product quality.
- 7.3 Specific end use(s): No additional relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Components with limit values that require monitoring at the workplace:

The product does not contain any hazardous ingredients with occupational exposure limits.

8.2 Exposure controls

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

Always maintain good housekeeping and follow general precautionary measures. Do not eat, drink or store food and beverages in areas where chemicals or specimens are used. Wash hands before breaks, after handling reagents and specimens, and at the end of the workshift.

Avoid contact with the skin.

Immediately remove all soiled and contaminated clothing.

Breathing equipment:

Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

(Continued on page 6)



Page 6/12

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories

Release date 27.04.2023 Version number 27 (replaces version 26)

Last alteration on 27.04.2023

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ **SHEATH**

(Continued from page 5)

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use appropriate air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use approved respiratory protection. Take precautions if chemical concentrations exceed the exposure limits (if any) listed above.

Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Material of gloves and breakthrough time of the glove material:

The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

· Eye/face protection

Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

Body protection:

Normal use: protect personal clothing from spatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution). Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

· Physical state

· Colour:

· Odour:

Odour threshold:

· Melting point/freezing point:

· Boiling point or initial boiling point and boiling range

· Flammability

· Lower and upper explosion limit

· Lower:

· Upper:

· Flash point:

· pH at 20 °C

Liquid Colourless Odourless

Not determined

Not determined

Not determined Not applicable

Not determined Not determined Not applicable

7.4

(Continued on page 7)

ENG



Page 7/12

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories

Release date 27.04.2023 Version number 27 (replaces version 26)

Not determined

Last alteration on 27.04.2023

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ **SHEATH**

(Continued from page 6)

· Viscosity:

· dynamic:

· Solubility

Fully miscible · Water: Not determined · Vapour pressure:

Density and/or relative density

· Density at 20 °C 1.006 g/cm3 Not determined · Relative density:

9.2 Other information

· Appearance:

· Form:

· Auto igniting Product is not self-igniting.

Explosive properties: Product does not present an explosion hazard.

None

None

None

None

· Water: 98.8 % · Solids content: 0.0 %

· Change in condition:

· Organic peroxides

· Corrosive to metals

Desensitised explosives

· Evaporation rate: Not determined

· Information with regard to physical hazard classes Explosives

· Flammable gases None · Aerosols None · Oxidising gases None Gases under pressure None · Flammable liquids None · Flammable solids None · Self-reactive substances and mixtures None Pyrophoric liquids None · Pyrophoric solids None · Self-heating substances and mixtures None · Substances and mixtures, which emit flammable gases in contact with water None · Oxidising liquids None · Oxidising solids None

SECTION 10: Stability and reactivity

• 10.1 Reactivity No further relevant information available.

(Continued on page 8)



Page 8/12

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories

Release date 27.04.2023 Version number 27 (replaces version 26)

Last alteration on 27.04.2023

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ **SHEATH**

(Continued from page 7)

- 10.2 Chemical stability:
 - · Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.

- 10.3 Possibility of hazardous reactions: No dangerous reactions known.
- 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

- · Acute toxicity Based on available data, the classification criteria are not met.
 - LD/LC50 values that are relevant for classification:
 - · Ingredients (100% pure substance/s): Not applicable.
- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Sensitisation:

Sensitization possible through skin contact.

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.
- Target organs/systems:

Immune system

11.2 Information on other hazards

· Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

SECTION 12: Ecological information

- 12.1 Toxicity
 - · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability: No further relevant information available.
- * 12.3 Bioaccumulative potential: No further relevant information available.

(Continued on page 9)



Page 9/12

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories

Release date 27.04.2023 Version number 27 (replaces version 26)

Last alteration on 27.04.2023

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ **SHEATH**

(Continued from page 8)

• 12.4 Mobility in soil: No further relevant information available.

12.5 Results of PBT and vPvB assessment

- · **PBT**: Not applicable · vPvB: Not applicable
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- 12.7 Other adverse effects:
 - · General notes: Generally not hazardous for water.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

There are no uniform EU regulations for the disposal of laboratory waste. In general, laboratory waste is under special supervision of the authorities.

· Recommendation for disposal of unused product:

Dispose in accordance with national, state and local regulations.

· European waste catalogue:

HP code: not applicable.

Consult the responsible regulatory body for the assignment of disposal codes according to the European Waste

The following waste disposal key numbers are possible:

18 01 06: chemicals consisting of or containing dangerous substances

Uncleaned packagings

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

Recommendation for disposal of packaging:

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

· Recommended cleaning agent: Water with cleansing agents, if necessary.

SECTION 14: Transport information

14.1 UN number or ID number

· ADR, ADN, IMDG, IATA None

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA None

(Continued on page 10)



Page 10/12

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories

Release date 27.04.2023 Version number 27 (replaces version 26)

Last alteration on 27.04.2023

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ **SHEATH**

(Continued from page 9)

14.3 Transport hazard class(es)

· ADR, ADN, IMDG, IATA

· Class None

14.4 Packing group

· ADR, IMDG, IATA None

14.5 Environmental hazards

· Marine pollutant: No

14.6 Special precautions for user Not applicable

14.7 Maritime transport in bulk according to IMO instruments

· Transport/Additional information

· ADR

· Remarks: Not restricted for transportation.

IMDG

· Remarks: Not restricted for transportation.

·IATA

· Remarks: Not restricted for transportation.

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.
 - · 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 - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

(Continued on page 11)



Page 11/12

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories

Release date 27.04.2023 Version number 27 (replaces version 26)

Last alteration on 27.04.2023

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ **SHEATH**

(Continued from page 10)

· 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.

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

SECTION 16: Other information

The information and recommendations contained herein are based upon information or tests believed to be reliable. Abbott Laboratories does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

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The information in this Safety Data Sheet (SDS) reflects the most current hazard information for this product.

· Complete text for H (Hazard) codes displayed in Section 3:

Note: The respective H statements apply to the pure substances.

H301 Toxic if swallowed.

H310 Fatal in contact with skin.

H311 Toxic in contact with skin.

Causes severe skin burns and eye damage. H314

May cause an allergic skin reaction. H317

Causes serious eye damage. H318

Fatal if inhaled. H330

H400 Very toxic to aquatic life.

Very toxic to aquatic life with long lasting effects. H410

EUH071 Corrosive to the respiratory tract.

· Contact supplier

Environmental Affairs & Product Safety

Tel.: +49 (0) 6122 58 0

Date of previous version: 28.03.2023 Version number of previous version: 26

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

(Continued on page 12)



Page 12/12

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories

Release date 27.04.2023 Version number 27 (replaces version 26)

Last alteration on 27.04.2023

Trade name: CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/ **SHEATH**

(Continued from page 11)

ICAO: International Civil Aviation Organisation

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: persistent, bioaccumulative and toxic

vPvB: very persistent and very bioaccumulative

Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 1: Acute toxicity – Category 1

Acute Tox. 2: Acute toxicity - Category 2

Skin Corr. 1B: Skin corrosion/irritation – Category 1B Skin Corr. 1C: Skin corrosion/irritation – Category 1C

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

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation - Category 1A

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

* Data compared to the previous version altered.