

# SAFETY DATA SHEET



## NxtScript Reverse Transcriptase, 85 U/uL

Version  
1.5

Revision Date:  
06/27/2024

Date of last issue: 04/11/2022  
Date of first issue: 12/20/2016

### SECTION 1. IDENTIFICATION

Product name : NxtScript Reverse Transcriptase, 85 U/uL

Product code : 07371527103

Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : Sandhoferstrasse  
Mannheim, 68305, Deutschland

Telephone : +496217590

Telefax : +496217592890

E-mail address : info.dia-sds@roche.com

Emergency telephone

Im Notfall: : Werkschutzzentrale Roche +49(0)621-759-2203  
Diagnostics GmbH

Giftnotruf: : Mainz +49(0)6131-19240

#### Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals  
Refer to product literature for further details.

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Not a hazardous substance or mixture.

#### GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

#### Other hazards

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
1,2,3-Propanetriol	Glycerol	56-81-5	$\geq 30 - < 60$ *
Reverse Transcriptase	Reverse Trans-	9068-38-6	$\geq 0 - < 0.1$ *

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\* Actual concentration or concentration range is withheld as a trade secret

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**SECTION 4. FIRST AID MEASURES**

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : None known.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : Carbon oxides
- Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

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Personal precautions, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).  
Keep in suitable, closed containers for disposal.

### SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Further information on storage stability : No decomposition if stored and applied as directed.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
1,2,3-Propanetriol	56-81-5	TWA (Mist)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Respirable mist)	3 mg/m <sup>3</sup>	CA BC OEL
		TWA (Mist)	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV (Mist)	10 mg/m <sup>3</sup>	CA QC OEL
Reverse Transcriptase	9068-38-6	IOEL	0.00006 mg/m <sup>3</sup>	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available

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Respiratory protection : No personal respiratory protective equipment normally required.

**Hand protection**

In case of contact through splashing:  
Material : Nitrile rubber  
Break through time : > 30 min  
Glove thickness : > 0.11 mm

In case of full contact:  
Material : butyl-rubber  
Break through time : > 480 min  
Glove thickness : > 0.4 mm

Remarks : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the material safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and break-through time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : colorless

Odor : unpleasant

Odor Threshold : No data available

pH : 7.5  
Concentration: 100 %

Melting point/range : No data available

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Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.13 g/cm <sup>3</sup>
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	No dangerous reaction known under conditions of normal use.

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tions	Stable under recommended storage conditions. No hazards to be specially mentioned.
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Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition products : No hazardous decomposition products are known.

## SECTION 11. TOXICOLOGICAL INFORMATION

### Acute toxicity

Not classified due to lack of data.

### Components:

### 1,2,3-Propanetriol:

Acute oral toxicity : LC50 (Mouse): 11,500 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): 275000 mg/m3  
Exposure time: 7 h  
Test atmosphere: vapor  
GLP: no  
Assessment: The component/mixture is minimally toxic after short term inhalation.

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg  
GLP: no

### Skin corrosion/irritation

Not classified due to lack of data.

### Components:

### 1,2,3-Propanetriol:

Species	:	Rabbit
Exposure time	:	24 h
Result	:	No skin irritation
GLP	:	no

### Serious eye damage/eye irritation

Not classified due to lack of data.

### Components:

### 1,2,3-Propanetriol:

Species	:	Rabbit
Result	:	No eye irritation
Exposure time	:	7 d
GLP	:	no

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**Respiratory or skin sensitization****Skin sensitization**

Not classified due to lack of data.

**Respiratory sensitization**

Not classified due to lack of data.

**Components:****1,2,3-Propanetriol:**

Assessment : Mild eye irritant, Mild respiratory irritant, No skin irritation

**Germ cell mutagenicity**

Not classified due to lack of data.

**Components:****1,2,3-Propanetriol:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Result: negative  
GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 476  
Result: negative  
GLP: No information available.

**Carcinogenicity**

Not classified due to lack of data.

**Components:****1,2,3-Propanetriol:**

Species : Rat, male and female  
Application Route : Oral  
Exposure time : 2 Years  
GLP : No information available.  
Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**Reproductive toxicity**

Not classified due to lack of data.

**Components:****1,2,3-Propanetriol:**

Effects on fertility : Test Type: Two-generation study  
Species: Rat, male and female

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Application Route: Oral  
Dose: 2000 mg/kg bw/day  
Fertility: NOAEL: 2,000 mg/kg body weight  
GLP: no

Effects on fetal development : Species: Rabbit, female  
Application Route: Oral  
Dose: 11.8, 54.8, 254.5, 1180 mg/kg bw/day  
Duration of Single Treatment: 29 d  
Developmental Toxicity: NOAEL: 1,180 mg/kg bw/day  
GLP: no

**STOT-single exposure**

Not classified due to lack of data.

**Components:****Reverse Transcriptase:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

**STOT-repeated exposure**

Not classified due to lack of data.

**Components:****Reverse Transcriptase:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

**Repeated dose toxicity****Components:****1,2,3-Propanetriol:**

Species : Rat, male and female  
NOAEL : 4580 mg/kg  
NOAEL : 4,580 mg/kg  
Application Route : Oral  
Exposure time : 90 d  
Number of exposures : daily  
Dose : 4580 - 25,800 mg/kg/day  
GLP : no

Species : Rat, male and female  
Application Route : Inhalation  
Test atmosphere : dust/mist  
Exposure time : 13 Weeks  
Number of exposures : 6 hours/day, 5 days/week  
Dose : 33, 165 and 660 mg/m<sup>3</sup>  
GLP : No information available.

Species : Rat



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NOAEL : 5040 mg/kg  
NOAEL : 5,040 mg/kg  
Application Route : Dermal  
Exposure time : 45 Weeks  
Number of exposures : 8 hours/day, 5 days/week  
Dose : 0.5-4.0 ml/kg  
GLP : no

Repeated dose toxicity - Assessment : Mild eye irritant, Mild respiratory irritant, No skin irritation

**Aspiration toxicity**

Not classified due to lack of data.

**Components:****Reverse Transcriptase:**

No data available

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****1,2,3-Propanetriol:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l  
End point: mortality  
Exposure time: 96 h  
Test Type: static test  
GLP: no

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 1,955 mg/l  
End point: mortality  
Exposure time: 48 h  
Test Type: static test  
Analytical monitoring: no  
GLP: no

Toxicity to algae/aquatic plants : (Scenedesmus quadricauda (Green algae)): > 10,000 mg/l  
End point: Growth rate  
Exposure time: 8 d  
Test Type: static test  
GLP: no

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 10,000 mg/l  
End point: Growth rate  
Exposure time: 16 h  
Test Type: static test  
GLP: No information available.

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Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

**Reverse Transcriptase:****Ecotoxicology Assessment**

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

**Persistence and degradability****Components:****1,2,3-Propanetriol:**

Biodegradability : aerobic  
Inoculum: activated sludge  
Concentration: 226 mg/l  
Result: Readily biodegradable.  
Biodegradation: 94 %  
Exposure time: 24 h  
GLP: no

**Bioaccumulative potential****Components:****1,2,3-Propanetriol:**

Partition coefficient: n-octanol/water : log Pow: -1.75 (25 °C)  
pH: 7.4  
Method: OECD Test Guideline 107  
GLP: no

**Reverse Transcriptase:**

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

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

- Waste from residues : Can be disposed as waste water, when in compliance with local regulations.
- Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable

**Domestic regulation****TDG**

Not regulated as a dangerous good

**Special precautions for user**

- Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

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**SECTION 15. REGULATORY INFORMATION**

**WHMIS Classification** : Not controlled.

**The ingredients of this product are reported in the following inventories:**

- AIIC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
Reverse Transcriptase
- NZIoC : On the inventory, or in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory

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KECI	: Not in compliance with the inventory
PICCS	: Not in compliance with the inventory
IECSC	: Not in compliance with the inventory
TCSI	: On the inventory, or in compliance with the inventory
TSCA	: Product contains substance(s) not listed on TSCA inventory.
TECI	: Not in compliance with the inventory

### Canadian lists

No substances are subject to a Significant New Activity Notification.

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## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

CA AB OEL	: Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	: Canada. British Columbia OEL
CA QC OEL	: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for air-borne contaminants
CA AB OEL / TWA	: 8-hour Occupational exposure limit
CA BC OEL / TWA	: 8-hour time weighted average
CA QC OEL / TWA EV	: Time-weighted average exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No

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1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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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.

CA / Z8 / 2304