

Symphony N1

Version 1.2

Revision Date 11-18-2013

Print Date 03-17-2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Symphony N1

Mat.-No./ Genisys-No. : 05279461001

Manufacturer or supplier's detailsCompany : Roche Diagnostics Limited
Charles AvenueAddress : Burgess Hill
RH15 9RY West Sussex

Telephone : +44 1444 256000

Telefax : +44 1444 256239

Emergency telephone : +49(0)621-759-2012 oder +49(0)621-759-4848 oder
number +49(0)8856-60-2629

Emergency telephone number:

In case of emergencies: : Health, Safety & +44 1444 256500 or +44 7802
(Roche Diagnostics Ltd.) Environment 260498

- +44 1444 256561 or +44 7710

Product Safety / Vigilance 391653

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Toxicology 24Hr help-line: : NPIS: +44 844 892 0111

Health Advice 24Hr help-line: NHS Direct: +44 845 4647

NHS 24: +44 8454 242424

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**Emergency Overview**

Physical state	liquid
Colour	reddish-violet
Odour	slight
	vinegar-like

GHS Classification

Skin irritation : Category 2

Serious eye damage : Category 1

GHS Label element

Hazard pictograms :



Signal word : Danger

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- Hazard statements : H315 Causes skin irritation.
H318 Causes serious eye damage.
- Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.
P280 Wear protective gloves.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P332 + P313 If skin irritation occurs: Get medical advice/attention.
P362 Take off contaminated clothing and wash before reuse.

Potential Health Effects**Carcinogenicity:**

- IARC** No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
- ACGIH** No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
- OSHA** No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
- NTP** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Preparation

Hazardous components

Chemical Name	CAS-No.	Concentration [%]
ethane-1,2-diol	107-21-1	>= 20 - < 30
acetic acid	64-19-7	>= 1 - < 5
Aluminum sulfate octadecahydrate	7784-31-8	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Consult a physician.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

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| 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 skin irritation persists, call a physician.
If on skin, rinse well with water.
If on clothes, remove clothes. |
| In case of eye contact | : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist. |
| If swallowed | : Clean mouth with water and drink afterwards plenty of water.
Keep respiratory tract clear.
Do NOT induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital. |
| Notes to physician | : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine. |

SECTION 5. FIREFIGHTING MEASURES

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| Suitable extinguishing media | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Unsuitable extinguishing media | : High volume water jet |
| Specific hazards during firefighting | : Do not allow run-off from fire fighting to enter drains or water courses. |
| Further information | : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. |
| Special protective equipment for firefighters | : Wear self contained breathing apparatus for fire fighting if necessary. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

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| Personal precautions, protective equipment and emergency procedures | : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8. |
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- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Do not breathe vapours/dust.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards.
- Materials to avoid :

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
ethane-1,2-diol	107-21-1	C	50 ppm 125 mg/m ³	OSHA P0
acetic acid	64-19-7	TWA	10 ppm	ACGIH
		STEL	15 ppm	ACGIH
		TWA	10 ppm 25 mg/m ³	NIOSH REL
		ST	15 ppm 37 mg/m ³	NIOSH REL
		TWA	10 ppm 25 mg/m ³	OSHA Z-1
		TWA	10 ppm 25 mg/m ³	OSHA P0
Aluminum sulfate octadecahydrate	7784-31-8	TWA	2 mg/m ³	OSHA P0
		TWA	2 mg/m ³	NIOSH REL

Personal protective equipment

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Hand protection	
Material	: Protective gloves
Remarks	: The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough 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	: Eye wash bottle with pure water Tightly fitting safety goggles Wear face-shield and protective suit for abnormal processing problems.
Skin and body protection	: impervious clothing Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hygiene measures	: When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: reddish-violet
Odour	: slight vinegar-like
pH	: acidic
Melting point/range	: no data available
Boiling point/boiling range	: no data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: no data available
Lower explosion limit	: no data available
Solubility(ies)	
Water solubility	: completely miscible
Auto-ignition temperature	: no data available
Thermal decomposition	: no data available

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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 reactions	: No decomposition if stored and applied as directed.
Conditions to avoid	: no data available
Incompatible materials	: Acids Bases Oxidizing agents
Hazardous decomposition products	: Carbon oxides

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**

Acute oral toxicity	: Acute toxicity estimate : > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	: Acute toxicity estimate : > 40 mg/l Exposure time: 4 h Test atmosphere: vapour Method: Calculation method

Components:**acetic acid:**

Acute oral toxicity	: LD50 Oral rat: 3,310 mg/kg
Acute dermal toxicity	: LD50 Dermal rabbit: 1016 µl/kg

Aluminum sulfate octadecahydrate:

Acute oral toxicity	: LD50 rat: > 9,000 mg/kg
	LD50 mouse: > 9,000 mg/kg

Skin corrosion/irritation**Product:**

Remarks: May cause skin irritation in susceptible persons.

Components:**acetic acid:**

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Result: Causes severe burns.

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation**Product:**

Remarks: May cause irreversible eye damage.

Components:**acetic acid:**

Remarks: May cause irreversible eye damage.

Aluminum sulfate octadecahydrate:

Result: Risk of serious damage to eyes.

Respiratory or skin sensitisation

no data available

Germ cell mutagenicity**Components:****acetic acid:**

Genotoxicity in vitro : Type: Chromosome aberration test in vitro
Method: Mutagenicity (in vitro mammalian cytogenetic test)
Remarks: In vitro tests did not show mutagenic effects

Germ cell mutagenicity- : Not mutagenic in Ames Test.
Assessment

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT - single exposure**Components:****acetic acid:**

Remarks: no data available

Aluminum sulfate octadecahydrate:

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

STOT - repeated exposure**Components:****acetic acid:**

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

Aluminum sulfate octadecahydrate:

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

Aspiration toxicity**Components:****acetic acid:**

no data available

Aluminum sulfate octadecahydrate:

no data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Components:**ethane-1,2-diol :**Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 96 hLC50 (Carassius auratus (goldfish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 hToxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202Toxicity to algae : EC0 (Scenedesmus quadricauda (Green algae)): > 10,000 mg/l
Exposure time: 7 dToxicity to bacteria : EC0 (Pseudomonas putida): > 10,000 mg/l
Exposure time: 16 h

Ecotoxicology Assessment

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

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

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

Other organisms relevant to the environment : no data available

acetic acid :

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 410 mg/l
Exposure time: 48 h

NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Ecotoxicology Assessment

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

Other organisms relevant to the environment : no data available

Aluminum sulfate octadecahydrate :

Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 235 mg/l
Exposure time: 96 h

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:****ethane-1,2-diol :**

Biodegradability : Biodegradation: 100 %
Exposure time: 28 d
Method: OECD Test Guideline 302

acetic acid :

Biodegradability : Biodegradation: 71 %
Exposure time: 5 d
Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

Bioaccumulative potential**Components:****ethane-1,2-diol :**

Partition coefficient: n-octanol/water : log Pow: -1.36

acetic acid :

Partition coefficient: n-octanol/water : log Pow: -0.31

Mobility in soil

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no data available

Other adverse effects

no data available

Product:

Regulation

40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Remarks

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues

: Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging

: Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION**International regulation****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 for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

Special precautions for user

Remarks

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

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SECTION 15. REGULATORY INFORMATION

OSHA Hazards : Corrosive to skin, Severe eye irritant

WHMIS Classification : D2B: Toxic Material Causing Other Toxic Effects
Corrosive Material

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Ethylene Glykol	107-21-1	5000	

SARA 302 : SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

ethane-1,2-diol	107-21-1	25 %
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Clean Air Act

The following chemical(s) are listed as HAP under the U.S. Clean Air Act, Section 12 (40 CFR 61):

ethane-1,2-diol	107-21-1	25 %
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This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

ethane-1,2-diol	107-21-1	25 %
acetic acid	64-19-7	4 %

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

acetic acid	64-19-7	4 %
Aluminum sulfate octadecahydrate	7784-31-8	3.52 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

acetic acid	64-19-7	4 %
Aluminum sulfate octadecahydrate	7784-31-8	3.52 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

ethane-1,2-diol	107-21-1	20 - 30 %
acetic acid	64-19-7	1 - 5 %
Aluminum sulfate octadecahydrate	7784-31-8	1 - 5 %

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Pennsylvania Right To Know

water	7732-18-5	50 - 70 %
ethane-1,2-diol	107-21-1	20 - 30 %
acetic acid	64-19-7	1 - 5 %
Aluminum sulfate octadecahydrate	7784-31-8	1 - 5 %

New Jersey Right To Know

water	7732-18-5	50 - 70 %
ethane-1,2-diol	107-21-1	20 - 30 %
acetic acid	64-19-7	1 - 5 %
Aluminum sulfate octadecahydrate	7784-31-8	1 - 5 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

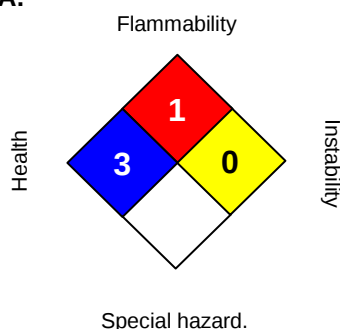
Inventories

AICS (Australia), DSL (Canada), IECSC (China), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	3
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

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.