

Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : ASSY, FILL DISP, ISH IVIEW BLUE NBT

Mat.-No./ Genisys-No. : 05262321001

Manufacturer or supplier's details

Company : Roche Diagnostics Limited

Charles Avenue

Address : 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

-

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	light green
Odour	none

GHS Classification

Reproductive toxicity : Category 1A

GHS Label element

Hazard pictograms

Signal word : Danger

Hazard statements : H360 May damage fertility or the unborn child.



Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

Precautionary statements : **Prevention:**

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P281 Use personal protective equipment as required.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention. **Storage:**

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

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 [%]
N,N-dimethylformamide	68-12-2	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.

Show this safety data sheet to the doctor in attendance.

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.



Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

In case of eye contact : Flush eyes with water as a precaution.

Remove contact lenses. Protect unharmed eye.

Keep eye wide open while rinsing.

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. 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

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 : The product itself does not burn.

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

Personal precautions, protective equipment and emergency procedures Environmental precautions : Use personal protective equipment.

Refer to protective measures listed in sections 7 and 8.

: 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.

Use neutralizing agents.



Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Do not breathe vapours/dust.

Avoid exposure - obtain special instructions before use.

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.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated

place.

Observe label precautions.

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
N,N-dimethylformamide	68-12-2	TWA	10 ppm	ACGIH
		TWA	10 ppm 30 mg/m3	NIOSH REL
		TWA	10 ppm 30 mg/m3	OSHA Z-1
		TWA	10 ppm 30 mg/m3	OSHA P0

Personal protective equipment

Respiratory protection : In the case of vapour formation use a respirator with an

approved filter.

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.



Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles

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 : light green

Odour : none

Odour Threshold : no data available

pH : ca. 10.0

Melting point/range : no data available
Boiling point/boiling range : no data available

Flash point :

does not flash

Upper explosion limit : no data available
Lower explosion limit : no data available
Density : 1.00 g/cm3

Solubility(ies)
Water solubility

: completely miscible

Auto-ignition temperature : no data available

Thermal decomposition : Hazardous decomposition products formed under fire

conditions.

Oxidizing properties : The substance or mixture is not classified as oxidizing.

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

: Keep away from heat and sources of ignition.

Risk of explosion.

Reacts with the following substances:

Oxidizing agents Reducing agents

Acids Bases



Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

No decomposition if stored and applied as directed.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents

Reducing agents

Acids Bases

Hazardous decomposition

products

: In case of fire hazardous decomposition products may be

produced such as:

Carbon oxides

nitrogen oxides (NOx)

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 : 29.51 mg/l

Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate : > 5,000 mg/kg

Method: Calculation method

Components:

N,N-dimethylformamide:

Acute oral toxicity : LD50 Oral rat: 2,800 mg/kg

Symptoms: Gastrointestinal disturbance

LD50 Oral mouse: 3,700 mg/kg

Acute inhalation toxicity : Acute toxicity estimate : 11 mg/l

Test atmosphere: vapour Method: Expert judgement

Acute dermal toxicity : LD50 Dermal rabbit: 1,500 mg/kg

Skin corrosion/irritation

Components:

N,N-dimethylformamide:

Remarks: May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation



Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

Components:

N,N-dimethylformamide:

Result: Eye irritation

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Components:

N,N-dimethylformamide:

Species: guinea pig

Result: Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Components:

N,N-dimethylformamide:

Genotoxicity in vitro : Type: Ames test

Result: negative

Carcinogenicity

Components:

N,N-dimethylformamide:

Carcinogenicity - : Animal testing did not show any carcinogenic effects.

Assessment

Reproductive toxicity

Components:

N,N-dimethylformamide:

Reproductive toxicity - : May damage the unborn child., Known human reproductive

Assessment toxicant

STOT - single exposure

Components:

N,N-dimethylformamide:

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

STOT - repeated exposure

Components:

N,N-dimethylformamide:

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

Aspiration toxicity

Components:

N,N-dimethylformamide:

No aspiration toxicity classification



Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

Further information

Components:

N,N-dimethylformamide:

Remarks: Solvents may degrease the skin.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

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

Other organisms relevant to

the environment

: no data available

Components:

N,N-dimethylformamide:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 10,600 mg/l

Exposure time: 96 h

LC50 (Oncorhynchus mykiss (rainbow trout)): 9,800 mg/l

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 6,300 mg/l

Exposure time: 96 h

Toxicity to daphnia and other

aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): 15,700 mg/l

Exposure time: 48 h

Toxicity to algae : EC50 (Chlorella pyrenoidosa): 890 mg/l

IC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l

Exposure time: 96 h

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): 2,000 mg/l

Exposure time: 0.08 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:

N,N-dimethylformamide:

Biodegradability : Zahn-Wellens Test

Result: Readily biodegradable.

Biodegradation: 97 % Exposure time: 7 d

Method: OECD Test Guideline 302

Remarks: According to the results of tests of biodegradability



Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

this product is considered as being readily biodegradable.

Result: Readily biodegradable. Biodegradation: > 90 %

Exposure time: 28 d

Method: OECD Test Guideline 301

Biochemical Oxygen : 900 mg/g

Demand (BOD) Incubation time: 5 d

Bioaccumulative potential

Components:

N,N-dimethylformamide:

Bioaccumulation : Remarks: Does not bioaccumulate.

Partition coefficient: n-

octanol/water

: log Pow: -0.85Method: OECD Test Guideline 107

Mobility in soil

no data available

Other adverse effects

no data available

Product:

Remarks

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).

Components:

N,N-dimethylformamide:

Additional ecological

information

: no data available

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.



Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

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

SECTION 15. REGULATORY INFORMATION

OSHA Hazards : Harmful by skin absorption., Moderate eye irritant, Reproductive

hazard

WHMIS Classification : D2A: Very Toxic Material Causing Other Toxic Effects

Toxic Material Causing Other Toxic Effects

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

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
N,N-Dimethylformamide	68-12-2	100	

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:

N,N-dimethylformamide 68-12-2 1 %

Clean Air Act

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

N,N-dimethylformamide 68-12-2 1 %



Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

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 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

N,N-dimethylformamide 68-12-2 1 %

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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

N,N-dimethylformamide 68-12-2 1 - 5 %

Pennsylvania Right To Know

water 7732-18-5 90 - 100 % N,N-dimethylformamide 68-12-2 1 - 5 %

New Jersey Right To Know

water 7732-18-5 90 - 100 % N,N-dimethylformamide 68-12-2 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



Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

Further information

NFPA: Flammability Instability Health

Special hazard.

HMIS III:

HEALTH	2*
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.