

SAFETY DATA SHEETS

This SDS packet was issued with item:

078015993

N/A

Material Safety Data Sheet



Authorization date: 07/19/1999
Revision date: 03/30/2011
Print Date: 03/30/2011
Version: 2

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product name: AST/GOT IFCC
Product number: 04571100190
Business area: Roche Professional Diagnostics
Product line: Roche/Hitachi
Supplier: Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
Site Phone Number: 1-800-428-5074

Emergency telephone number:
CHEMTREC:
1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description 1: Bottle R1

Components	CAS Number	Weight %	OSHA PEL:	OSHA STEL:	ACGIH TLV:	ACGIH STEL:
Aspartic acid	56-84-8	1-5	NA	NA	NA	NA
Tris	77-86-1	1-5	NA	NA	NA	NA
Sodium azide	26628-22-8	0.01-<0.1	NA	NA	NA	0.29 mg/m ³ Ceiling 0.11 ppm Ceiling

Description 2: Bottle R1a

Components	CAS Number	Weight %	OSHA PEL:	OSHA STEL:	ACGIH TLV:	ACGIH STEL:
NADH	606-68-8	0.01-<0.1	NA	NA	NA	NA
Aspartic acid	56-84-8	1-5	NA	NA	NA	NA
Mannitol	87-78-5	90 - 95	NA	NA	NA	NA

3. HAZARDS IDENTIFICATION

Emergency Overview

NFPA Ratings: Health= 1 Flammability= 0 Reactivity= 0 Special= I

Special Definitions: A=Allergen CA=Carcinogen CO=Corrosive F=Flammable H=Harmful I=Irritant Ox=Oxidizer PB=Potential Biohazard
R=Reproductive S=Sensitizer T=Toxic T+=Highly Toxic W=Water Reactive

Principle routes of exposure: Ingestion, inhalation, skin and/or eye contact.

Inhalation: Bottle R1a. May cause irritation of respiratory tract. Avoid breathing dust.

Ingestion: Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea

Skin contact: May cause irritation in contact with skin.

Eye contact: Avoid contact with skin and eyes. Contact with eyes may cause irritation.

Sensitization or Odor threshold: The following chemical(s) may cause sensitization, be absorbed via skin, and/or has an odor threshold for detection:

Medical conditions aggravated by exposure: None known

Additional information: None

4. FIRST AID MEASURES

Inhalation: Consult a physician. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.

Ingestion: Call a physician immediately. Do not induce vomiting without medical advice.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Notes to physician: None determined

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use dry chemical, CO₂, water spray or "alcohol" foam.

Unusual hazards: None known.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Evacuate personnel to safe areas. Remove all sources of ignition.

Environmental precautions: Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not flush into surface water or sanitary sewer system. Do not let product enter drains.

Methods for cleaning up: Never return spills in original containers for re-use. Soak up with oil absorbent material. Sweep up or vacuum (if powder) or soak up with inert absorbent material (if liquid), then place into a suitable clean, dry, closed container, and label for disposal.

7. HANDLING AND STORAGE

Handling: Protect from contamination. Wear personal protective equipment.

Storage: No special precautions required.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering measures: Not applicable.

Personal Protective Equipment

Respiratory protection: Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation, 29CFR1910.134. Always use a NIOSH approved respirator when necessary.

Hand protection: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Skin and body protection: Wear appropriate body protection to prevent skin contact.

Eye protection: Wear appropriate eye protection to prevent eye contact.

Hygiene measures: When using, do not eat, drink or smoke. Keep away from food and drink. Wash hands before breaks and at the end of workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: R1a is a white solid.

pH: Bottle R1 pH = 7-8

Physical state: Bottle R1 is liquid. Bottle R1a is solid.

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Polymerization: None under normal processing.

Hazardous decomposition products: Thermal decomposition can lead to release of irritating gases and vapours. Carbon monoxide.

Materials to avoid: Incompatible with strong acids and bases. Oxidising agents (strong). Heavy metals.

11. TOXICOLOGICAL INFORMATION

Components	NIOSH - Selected LD50s and LC50s:	NIOSH Pocket Guide - Target Organs:
Aspartic acid	=9000 mg/kg Oral LD50 Rat	
Tris	=5900 mg/kg Oral LD50 Rat	

11. TOXICOLOGICAL INFORMATION

Sodium azide	=20 mg/kg Dermal LD50 Rabbit =50 mg/kg Dermal LD50 Rat =27 mg/kg Oral LD50 Rat	eyes CNS skin CVS kidneys
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Components	NIOSH - Selected LD50s and LC50s:	NIOSH Pocket Guide - Target Organs:
Aspartic acid	=9000 mg/kg Oral LD50 Rat	

Inhalation: No additional data available
Skin: No additional data available
Oral: No additional data available
Mutagenic effects: No data is available on the product itself
Reproductive toxicity: No data is available on the product itself

12. ECOLOGICAL INFORMATION

Bioaccumulation: Not determined
Aquatic toxicity: No data is available on the product itself
Ecotoxicity effects: No data is available on the product itself

U.S. EPA, RCRA, CERCLA, SARA, or DGC information on persistent, bioaccumulative, and toxic chemicals (PBTs):
The following chemicals are listed under the U.S. EPA regulations of RCRA, CERCLA, SARA, or DGC:

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous.

14. TRANSPORT INFORMATION

Is product hazardous to ship? No.
DOT

Proper shipping name: None			
UN Number: Not applicable	Hazard class: Not applicable	Subsidiary risk: Not applicable	Packing group: Not applicable

ICAO/IATA

Proper shipping name: None			
UN Number: Not applicable	Hazard class: Not applicable	Subsidiary risk: Not applicable	Packing group: Not applicable

15. REGULATORY INFORMATION

U.S. Regulations:

U.S. CERCLA/SARA/TSCA Regulatory Information: The following chemicals are listed under the following TSCA/SARA/CERCLA lists. Refer to TSCA regulation if you need a definition for acronyms that may be shown in the TSCA Inventory field in the table below

Components	CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)	CERCLA/SARA 304 RQ (40 CFR Table 302.4)	SARA 313 Emission reporting	TSCA Inventory
Aspartic acid				Present
Tris				Present
Sodium azide	500 lb TPQ	1000 lb final RQ 454 kg final RQ	Listed	Present

Components	CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)	CERCLA/SARA 304 RQ (40 CFR Table 302.4)	SARA 313 Emission reporting	TSCA Inventory
NADH				Present
Aspartic acid				Present

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Components	CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)	CERCLA/SARA 304 RQ (40 CFR Table 302.4)	SARA 313 Emission reporting	TSCA Inventory
Mannitol				Present

U.S. Clean Water Act (CWA)/ California Proposition 65: The following chemicals are listed under the CWA and/or California Proposition 65:

Canadian Regulations:

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

Components	Canada - WHMIS: Classifications of Substances:
Aspartic acid	Uncontrolled product according to WHMIS classification criteria
Tris	D2B
Sodium azide	D1A

Components	Canada - WHMIS: Classifications of Substances:
Aspartic acid	Uncontrolled product according to WHMIS classification criteria

16. OTHER INFORMATION

Reason for revision: Section 2 was revised. Hazard information in Section 3 was updated or revised. Section 9 was revised.
References: None.
Additional advice: None
Prepared by: Roche Diagnostics, Health & Safety Department, MSDS Contact: 317-521-7425 or 317-521-7505

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End of Safety Data Sheet

SAFETY DATA SHEET



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Version
1.0

Revision Date:
11-10-2015

Date of last issue: -
Date of first issue: 11-10-2015

SECTION 1. IDENTIFICATION

Product name : AST (ASAT/GOT)

Mat.-No./ Genisys-No. : 04571118190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
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Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone:

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS Label element

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Substance name : GPT IFCC, Hitachi 917, R2 for 1730576, a-KG

Hazardous ingredients

No hazardous ingredients

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.

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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.

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	: No hazardous combustion products are known
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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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	: Normal measures for preventive fire protection.
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fire and explosion

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.

Technical measures/Precautions : See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 7.5

Melting point/range : No data available

Boiling point/boiling range : No data available

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Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapor pressure	: No data available
Relative vapor density	: No data available
Relative density	: No data available
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
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	: Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	: No data available
Incompatible materials	: No data available
Hazardous decomposition products	: No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

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Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization: Not classified based on available information.

Respiratory sensitization: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

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.

OSHA

No ingredient 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 ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

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

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Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: 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).

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.

SECTION 14. TRANSPORT INFORMATION

International Regulation

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 for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

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Ingredients	CAS-No.	Component RQ (lbs)	Component RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 311/312 Hazards : No SARA Hazards

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

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

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).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

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).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

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

Sodium azide	26628-22-8	0 - 0.1 %
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Pennsylvania Right To Know

Water	7732-18-5	90 - 100 %
Sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

Water	7732-18-5	90 - 100 %
Disodium 2-oxoglutarate	305-72-6	1 - 5 %

California Prop. 65

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

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CH INV	: On the inventory, or in compliance with the inventory
TSCA	: Not On TSCA Inventory Disodium 2-oxoglutarate
DSL	: All components of this product are on the Canadian DSL
AICS	: On the inventory, or in compliance with the inventory
NZIoC	: On the inventory, or in compliance with the inventory
ENCS	: Not in compliance with the inventory Water Disodium 2-oxoglutarate Tris hydrochloride
ISHL	: Not in compliance with the inventory Disodium 2-oxoglutarate Tris hydrochloride
KECI	: Not in compliance with the inventory Disodium 2-oxoglutarate
PICCS	: Not in compliance with the inventory Disodium 2-oxoglutarate
IECSC	: Not in compliance with the inventory Disodium 2-oxoglutarate

TSCA list

No substances are subject to a Significant New Use Rule.

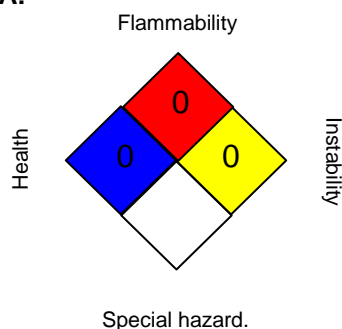
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION**Full text of other abbreviations**

(Q)SAR - (Quantitative) Structure Activity Relationship; ASTM - American Society for the Testing of Materials; bw - Body weight; DIN - Standard of the German Institute for Standardisation; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; 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; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISO - International Organisation for Standardization; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic

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substance; REACH - Regulation (EC) No 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; UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative; DSL - Domestic Substances List (Canada); KECI - Korea Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); AICS - Australian Inventory of Chemical Substances; IECSC - Inventory of Existing Chemical Substances in China; ENCS - Existing and New Chemical Substances (Japan); ISHL - Industrial Safety and Health Law (Japan); PICCS - Philippines Inventory of Chemicals and Chemical Substances; NZIoC - New Zealand Inventory of Chemicals; TCSI - Taiwan Chemical Substance Inventory; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; DOT - Department of Transportation; EHS - Extremely Hazardous Substance; HMIS - Hazardous Materials Identification System; MSHA - Mine Safety and Health Administration; NFPA - National Fire Protection Association; RCRA - Resource Conservation and Recovery Act; RQ - Reportable Quantity; SARA - Superfund Amendments and Reauthorization Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; GLP - Good Laboratory Practice; ERG - Emergency Response Guide; NTP - National Toxicology Program; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods

Further information**NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

Revision Date : 11-10-2015

The information provided in this Material 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.

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