

according to Regulation (EC) No. 1907/2006

Creation Date 14-Sep-2016 Revision Date 06-Oct-2023 Revision Number 5

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Description: <u>Dasatinib monohydrate</u>
Cat No.: <u>Dasatinib monohydrate</u>
462320000; 462320010

CAS No 863127-77-9

Molecular Formula C22 H26 CI N7 O2 S . H2 O

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Laboratory chemicals.
Uses advised against No Information available

1.3. Details of the supplier of the safety data sheet

Company

EU entity/business name

Thermo Fisher Scientific

Janssen Pharmaceuticalaan 3a, 2440 Geel, Belgium

UK entity/business name

Fisher Scientific UK
Bishop Meadow Road.

Bisnop ivieadow Road,

Loughborough, Leicestershire LE11 5RG, United Kingdom

Swiss distributor - Fisher Scientific AG Neuhofstrasse 11, CH 4153 Reinach

Tel: +41 (0) 56 618 41 11

e-mail - infoch@thermofisher.com

E-mail address begel.sdsdesk@thermofisher.com

1.4. Emergency telephone number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

customers in Switzerland:

Tox Info Suisse Emergency Number: 145 (24hr)

Tox Info Suisse: +41-44 251 51 51 (Emergency number from abroad)

Chemtrec (24h) Toll-Free: 0800 564 402 Chemtrec Local: +41-43 508 20 11 (Zurich)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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CLP Classification - Regulation (EC) No 1272/2008

Physical hazards

Based on available data, the classification criteria are not met

Health hazards

Acute oral toxicity

Skin Corrosion/Irritation

Serious Eye Damage/Eye Irritation

Category 2 (H315)

Carcinogenicity

Category 1 (H318)

Carcinogenicity

Category 2 (H351)

Reproductive Toxicity

Category 2 (H361)

Specific target organ toxicity - (repeated exposure)

Category 1 (H372)

Environmental hazards

Chronic aquatic toxicity Category 1 (H410)

Full text of Hazard Statements: see section 16

2.2. Label elements



Signal Word

Danger

Hazard Statements

- H301 Toxic if swallowed
- H315 Causes skin irritation
- H318 Causes serious eve damage
- H351 Suspected of causing cancer
- H361 Suspected of damaging fertility or the unborn child
- H372 Causes damage to organs through prolonged or repeated exposure
- H410 Very toxic to aquatic life with long lasting effects

Precautionary Statements

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting

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

2.3. Other hazards

No information available

This product does not contain any known or suspected endocrine disruptors

Toxic to terrestrial vertebrates

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Component	CAS No	EC No	Weight %	CLP Classification - Regulation (EC) No 1272/2008
N-(2-Chloro-6-methylphenyl)-2-[[6-[4-(2-hyd roxyethyl)piperazin-1-yl]-2-methylpyrimidin-4-yl]amino]-1,3-thiazole-5-carboxamide hydrate			>95	Acute Tox. 3 (H301) Skin Irrit. 2 (H315) Eye Damage 1 (H318) Repr. 2 (H361) Carc. 2 (H351)
				STOT Rep. Exp. 1 (H372) Aquatic Chronic 1 (H410)
Dasatinib	302962-49-8		-	Acute Tox. 3 (H301) Skin Irrit. 2 (H315) Eye Damage 1 (H318) Repr. 2 (H361) Carc. 2 (H351) STOT Rep. Exp. 1 (H372) Aquatic Chronic 1 (H410)

Full text of Hazard Statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General Advice Show this safety data sheet to the doctor in attendance. Immediate medical attention is

required.

Eye Contact In the case of contact with eyes, rinse immediately with plenty of water and seek medical

advice.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. Immediate medical

attention is required.

Ingestion Do NOT induce vomiting. Call a physician or poison control center immediately.

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth

method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Immediate medical attention is required.

Self-Protection of the First Aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination.

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

None reasonably foreseeable. Causes severe eye damage.

4.3. Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

Dasatinib monohydrate

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Do not allow run-off from fire-fighting to enter drains or water courses.

Hazardous Combustion Products

Carbon dioxide (CO₂), Carbon monoxide (CO), Hydrogen chloride, Nitrogen oxides (NOx), Sulfur oxides.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Thermal decomposition can lead to release of irritating gases and vapors.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

6.2. Environmental precautions

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system. Prevent product from entering drains. Local authorities should be advised if significant spillages cannot be contained.

6.3. Methods and material for containment and cleaning up

Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Wear personal protective equipment/face protection. Do not get in eyes, on skin, or on clothing. Avoid dust formation. Use only under a chemical fume hood. Do not breathe (dust, vapor, mist, gas). Do not ingest. If swallowed then seek immediate medical assistance.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. To maintain product quality. Store in freezer.

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Technical Rules for Hazardous Substances (TRGS) 510

Storage Class (LGK) (Germany)

Storage Class/LGK 6.1C

Switzerland - Storage of hazardous substances

Storage class - SC 6.1

https://www.kvu.ch/de/themen/stoffe-und-produkte https://www.kvu.ch/fr/themes/substances-et-produits https://www.kvu.ch/it/temi/sostanze-e-prodotti

7.3. Specific end use(s)

Use in laboratories

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)

No information available

Predicted No Effect Concentration (PNEC)

No information available.

8.2. Exposure controls

Engineering Measures

Ensure that eyewash stations and safety showers are close to the workstation location.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

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Personal protective equipment

Eye Protection Goggles (European standard - EN 166)

Hand Protection Protective gloves

Glove materia	I Breakthrough time	Glove thickness	EU standard	Glove comments
Nitrile rubber	See manufacturers	-	EN 374	(minimum requirement)
Neoprene	recommendations			
Natural rubber				
PVC				

Skin and body protection Long sleeved clothing.

Inspect gloves before use. observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information) gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, gloves with care avoiding skin contamination.

Respiratory Protection When workers are facing concentrations above the exposure limit they must use

appropriate certified respirators.

To protect the wearer, respiratory protective equipment must be the correct fit and be used

and maintained properly

Large scale/emergency use Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits

> are exceeded or if irritation or other symptoms are experienced Recommended Filter type: Particulates filter conforming to EN 143

Small scale/Laboratory use Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure

limits are exceeded or if irritation or other symptoms are experienced.

Recommended half mask:- Particle filtering: EN149:2001 When RPE is used a face piece Fit Test should be conducted

Environmental exposure controls Prevent product from entering drains. Do not allow material to contaminate ground water

system. Local authorities should be advised if significant spillages cannot be contained.

Solid

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State Solid

White Pale yellow **Appearance** Odor No information available No data available **Odor Threshold Melting Point/Range** No data available **Softening Point** No data available **Boiling Point/Range** No information available

Flammability (liquid) Not applicable

Flammability (solid,gas) No information available

Explosion Limits No data available

Flash Point No information available Method - No information available

No data available **Autoignition Temperature Decomposition Temperature** No data available

No information available Ha

Viscosity Not applicable Solid

No information available **Water Solubility** Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Vapor Pressure No data available No data available **Density / Specific Gravity**

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Bulk Density No data available

Vapor Density Not applicable Solid

Particle characteristics No data available

9.2. Other information

Molecular Formula C22 H26 Cl N7 O2 S . H2 O

Molecular Weight 506.02

Evaporation Rate Not applicable - Solid

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

None known, based on information available

10.2. Chemical stability

No information available.

10.3. Possibility of hazardous reactions

Hazardous PolymerizationNo information available.Hazardous ReactionsNone under normal processing.

10.4. Conditions to avoid

Incompatible products.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Carbon dioxide (CO₂). Carbon monoxide (CO). Hydrogen chloride. Nitrogen oxides (NOx).

Sulfur oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Product Information

(a) acute toxicity;

Oral Category 3
Dermal No data available
Inhalation No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
N-(2-Chloro-6-methylphenyl)-2-[[6-[4-(2-hyd	100 mg/kg (rat)	=	=
roxyethyl)piperazin-1-yl]-2-methylpyrimidin-			
4-yl]amino]-1,3-thiazole-5-carboxamide			
hydrate			!

(b) skin corrosion/irritation; Category 2

(c) serious eye damage/irritation; Category 1

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(d) respiratory or skin sensitization;

Respiratory No data available Skin No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; Category 2

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; Category 2

Reproductive Effects SUSPECT REPRODUCTIVE HAZARD - CONTAINS MATERIAL WHICH MAY INJURE

UNBORN CHILD (CAUSE BIRTH DEFECTS) (BASED ON ANIMAL DATA).

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; Category 1

Target Organs No information available.

(j) aspiration hazard; Not applicable

Solid

Symptoms / effects,both acute and No information available.

delayed

11.2. Information on other hazards

Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any

known or suspected endocrine disruptors.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity effects Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic

environment. Data from closely analogous substances.

12.2. Persistence and degradability

Degradation in sewage treatment plant

Contains substances known to be hazardous to the environment or not degradable in waste

water treatment plants.

12.3. Bioaccumulative potential No information available

12.4. Mobility in soil No information available

12.5. Results of PBT and vPvB

assessment

No data available for assessment.

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12.6. Endocrine disrupting

properties

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects **Persistent Organic Pollutant Ozone Depletion Potential**

This product does not contain any known or suspected substance This product does not contain any known or suspected substance

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from Residues/Unused

Products

Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations. Should not

be released into the environment.

Contaminated Packaging Dispose of this container to hazardous or special waste collection point.

According to the European Waste Catalog, Waste Codes are not product specific, but **European Waste Catalogue (EWC)**

application specific.

Other Information Do not flush to sewer. Waste codes should be assigned by the user based on the

application for which the product was used. Do not empty into drains. Do not let this

chemical enter the environment.

Switzerland - Waste Ordinance Disposal should be in accordance with applicable regional, national and local laws and

regulations. Ordinance on the Avoidance and the Disposal of Waste (Waste Ordinance,

ADWO) SR 814.600

https://www.fedlex.admin.ch/eli/cc/2015/891/en

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO

<u>14.1. UN numbe</u>r UN2811

TOXIC SOLID, ORGANIC, N.O.S. 14.2. UN proper shipping name

Technical Shipping Name Dasatinib monohydrate

14.3. Transport hazard class(es) 6.1 Ш

14.4. Packing group

ADR

UN2811 14.1. UN number

14.2. UN proper shipping name TOXIC SOLID, ORGANIC, N.O.S.

Technical Shipping Name Dasatinib monohydrate

14.3. Transport hazard class(es) 6.1 14.4. Packing group Ш

IATA

14.1. UN number

14.2. UN proper shipping name TOXIC SOLID, ORGANIC, N.O.S.

Technical Shipping Name Dasatinib monohydrate

14.3. Transport hazard class(es) 6.1 14.4. Packing group Ш

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14.5. Environmental hazards Dangerous for the environment

Product is a marine pollutant according to the criteria set by IMDG/IMO

14.6. Special precautions for user No special precautions required.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable, packaged goods

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	EINECS	ELINCS	NLP	IECSC	TCSI	KECL	ENCS	ISHL
N-(2-Chloro-6-methylphenyl)-2-[[6-	863127-77-9	-	-	-	-	X	-	-	-
[4-(2-hydroxyethyl)piperazin-1-yl]-									
2-methylpyrimidin-4-yl]amino]-1,3-t									
hiazole-5-carboxamide hydrate									
Dasatinib	302962-49-8	-	-	-	-	Х	-	-	-

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
N-(2-Chloro-6-methylphenyl)-2-[[6- [4-(2-hydroxyethyl)piperazin-1-yl]- 2-methylpyrimidin-4-yl]amino]-1,3-t hiazole-5-carboxamide hydrate		-	-	-	-	-	-	-
Dasatinib	302962-49-8	-	-	-	1	-	-	-

Legend: X - Listed '-' - Not Listed KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

Authorisation/Restrictions according to EU REACH

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization		REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
N-(2-Chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)piperazin-1-yl]-2- methylpyrimidin-4-yl]amino]-1,3-thia zole-5-carboxamide hydrate		-	-	-
Dasatinib	302962-49-8	-	-	-

Not applicable

Seveso III Directive (2012/18/EC)

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements
N-(2-Chloro-6-methylphenyl) -2-[[6-[4-(2-hydroxyethyl)pip erazin-1-yl]-2-methylpyrimidi n-4-yl]amino]-1,3-thiazole-5- carboxamide hydrate		Not applicable	Not applicable
Dasatinib	302962-49-8	Not applicable	Not applicable

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

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Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)?

Not applicable

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at

Take note of Directive 94/33/EC on the protection of young people at work

Take note of Dir 92/85/EC on the protection of pregnant and breastfeeding women at work

National Regulations

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

WGK Classification

Water endangering class = 3 (self classification)

Swiss Regulations

Article 4 para. 4 of the Ordinance on the protection of young people in the workplace (SR 822.115) and Article 1 lit. f of the EAER regulation on hazardous work and young people (SR 822.115.2).

Take note on Article 13 Maternity Ordinance (SR 822.111.52) with regards expectant and nursing mothers.

15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3

H301 - Toxic if swallowed

H315 - Causes skin irritation

H318 - Causes serious eye damage

H351 - Suspected of causing cancer

H361 - Suspected of damaging fertility or the unborn child

H372 - Causes damage to organs through prolonged or repeated exposure

H410 - Very toxic to aquatic life with long lasting effects

Legend

CAS - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances/EU List of Notified Chemical Substances

Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances IECSC - Chinese Inventory of Existing Chemical Substances

ENCS - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

TWA - Time Weighted Average IARC - International Agency for Research on Cancer

ACGIH - American Conference of Governmental Industrial Hygienists **DNEL** - Derived No Effect Level

Predicted No Effect Concentration (PNEC)

RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50%

LD50 - Lethal Dose 50% EC50 - Effective Concentration 50%

NOEC - No Observed Effect Concentration PBT - Persistent, Bioaccumulative, Toxic

POW - Partition coefficient Octanol:Water vPvB - very Persistent, very Bioaccumulative

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ADR - European Agreement Concerning the International Carriage of

Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime

Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from

Ships

ATE - Acute Toxicity Estimate

VOC - (volatile organic compound)

Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

Chemical incident response training.

Creation Date 14-Sep-2016 Revision Date 14-Sep-2016 06-Oct-2023

Revision Summary SDS sections updated.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006. COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No. 1907/2006

For Switzerland - Compiled in accordance with the technical provisions referred to in Annex 2, Number 3, ChemO (SR 813.11 - Ordinance on Protection against Dangerous Substances and Preparations).

Disclaimer

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

End of Safety Data Sheet