

Eprinex®, Eprinex® Multi, Ivomec Eprinex® (Finished product)

Version Revision Date: SDS Number: Date of last issue: 10/28/2019 2.0 06/10/2020 000000049068 Date of first issue: 10/28/2019

SECTION 1. IDENTIFICATION

Product name : Eprinex®, Eprinex® Multi, Ivomec Eprinex® (Finished prod-

uct)

Synonyms : Pour-On for: for Beef and Dairy Cattle, sheep and goats

With API: Eprinomectin 5 mg/ml

Manufacturer or supplier's details

Company name of supplier : Boehringer Ing. Pharma GmbH & Co.KG

Address : Binger Straße 173

Ingelheim 55216

Germany

Telephone : +498007790900

Prepared by : EHS-Services@Boehringer-Ingelheim.com

Emergency telephone num-

be

Int. Emergency Telephone number: +1 703-527-3887

Chemtrec 24-hours

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Safety Data Sheet only for the professional user.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Reproductive toxicity : Category 2

Effects on or via lactation

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361 Suspected of damaging fertility or the unborn child.

H362 May cause harm to breast-fed children.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.



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P202 Do not handle until all safety precautions have been read

and understood.

P263 Avoid contact during pregnancy/ while nursing.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

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 dis-

posal plant.

Other hazards

The pharmacological effect of the medicament has to be considered (see package leaflet). This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : organic

Components

Chemical name	CAS-No.	Concentration (% w/w)
Eprinomectin	123997-26-2	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately (show the label where possible).

First Aid responders should pay attention to self-protection

and use the recommended protective clothing

Remove from exposure, lie down.

Take off immediately all contaminated clothing.

Victim to lie down in the recovery position, cover and keep him

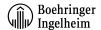
warm.

If inhaled : Move to fresh air.

In case of skin contact : Wash off immediately with plenty of water.

In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.

Keep eye wide open while rinsing.



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If swallowed : Rinse mouth.

Drink plenty of water.

Most important symptoms and effects, both acute and

delayed

Suspected of damaging fertility or the unborn child.

May cause harm to breast-fed children.

Notes to physician : Observe the summary of product characteristics of proprietary

medicinal products

Symptomatic treatment (decontamination, vital functions).

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Water

Dry chemical

Foam

Carbon dioxide (CO2)

Specific hazards during fire-

fighting

In case of fire and/or explosion do not breathe fumes.

Can be released in case of fire:

Carbon oxides

Nitrogen oxides (NOx)

Product itself is non-combustible; fire extinguishing method of

surrounding areas must be considered.

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

In the event of fire, wear self-contained breathing apparatus.

complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Wear personal protective equipment.

Ensure adequate ventilation.

High risk of slipping due to leakage/spillage of product.

Environmental precautions : Do not flush into surface water or sanitary sewer system.

Methods and materials for

containment and cleaning up

Pick up and transfer to properly labelled containers.

SECTION 7. HANDLING AND STORAGE

Advice on protection against

fire and explosion

No special protective measures against fire required.

The product is not flammable.



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Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.

Conditions for safe storage : No special storage conditions required.

Materials to avoid : Keep away from food, drink and animal feedingstuffs.

Observe joint storage prohibition.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	Basis	Category	Values	Remark
Eprinomectin 123997-26-2	BIEL	3A	10 μg/m3	
	BIPC	1b		

Abbreviations:

BIEL = Boehringer Ingelheim Exposure Limit (internal value)

BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit)

BIPC = Boehringer Ingelheim Pregnancy Category

BIPC 1b: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. There is evidence in animals and/or humans that this material has the potential to cause harm to the unborn at exposure levels exceeding the BIEL value.

Engineering measures : Local exhaust

Emergency sprinkling nozzle

Personal protective equipment

Respiratory protection : Use NIOSH approved respiratory protection.

Hand protection

Material : Nitrile rubber Glove thickness : 0.43 mm

Directive : Protective gloves against chemicals and micro-organisms

Protective index : Class 6

Remarks : The break through time depends amongst other things on the

material, the thickness and the type of glove and therefore

has to be measured for each case.

Eye protection : Safety glasses with side-shields

Skin and body protection : Laboratory: laboratory coat; Factory: disposable Overall.

Protective measures : Handle in accordance with good industrial hygiene and safety

practice.

Avoid contact with skin, eyes and clothing.



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Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warran-

ty given by the manufacturer for the safe function.

Hygiene measures : General industrial hygiene practice.

Wash hands and face before breaks and immediately after

handling the product.

Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : colourless, yellow

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/range : Not applicable

Boiling point/boiling range : No data available

Flash point : 428 °F / 220 °C

Evaporation rate : Not applicable

Flammability (solid, gas) : Not applicable

Self-ignition : Not auto-flammable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

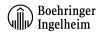
Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : 0.91 - 0.92

Bulk density : Not applicable

Solubility(ies)



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Water solubility : of low solubility

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : Not applicable

Explosive properties : Not tested

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reac-

tions

No dangerous reaction known under conditions of normal use.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition

products

No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: 2,047 mg/kg

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: 2,515 mg/kg

Method: Calculation method

Components:

Eprinomectin:

Acute oral toxicity : LD50 (Mouse): 70 mg/kg

LD50 (Rat): 55 mg/kg



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Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Not classified based on available information.

Components:

Eprinomectin:

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Eprinomectin:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Eprinomectin:

Test Type : Mouse Local Lymph Node Assay (LLNA)

Species : Guinea pig

Result : Does not cause skin sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Components:

Eprinomectin:

Genotoxicity in vitro : Test Type: Ames test

Test system: S. typhimurium and E. coli

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: V79 cells (Chinese hamster)

Result: negative

Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells

Result: negative



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Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Eprinomectin:

Remarks : The chemical structure does not suggest such an effect.

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.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

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.

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

May cause harm to breast-fed children.

Components:

Eprinomectin:

Effects on fertility : Remarks: No data available

Effects on foetal develop-

ment

Test Type: Two-generation study

Species: Rat

Application Route: Ingestion Dose: 0, 1, 2,5-3, 6 mg/kg /day

General Toxicity Maternal: NOEL: 1 mg/kg body weight Developmental Toxicity: NOEL: 1 mg/kg body weight Remarks: Did not show teratogenic effects in animal experi-

ments

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral Dose: 0,5 to 8 mg/kg/day

General Toxicity Maternal: NOEL: 0.5 mg/kg body weight Embryo-foetal toxicity: NOAEL: 0.5 mg/kg body weight Remarks: Did not show teratogenic effects in animal experi-

ments

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experi-

ments., Effects on or via lactation



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STOT - single exposure

Not classified based on available information.

Components:

Eprinomectin:

Remarks : Not classified due to data which are conclusive although insuf-

ficient for classification.

STOT - repeated exposure

Not classified based on available information.

Components:

Eprinomectin:

Exposure routes : Ingestion

Target Organs : Central nervous system

Assessment : The substance or mixture is classified as specific target organ

toxicant, repeated exposure, category 1.

Repeated dose toxicity

Components:

Eprinomectin:

Species : Rabbit

NOEL : 1.5 mg/kg

Application Route : Oral

Exposure time : 28-day

Dose : 1,5 - 25 mg/kg/day

Species : Rat
NOEL : 5 mg/kg
Application Route : Oral

Dose : 1 - 30 mg/kg/day

Species : Rat

NOEL : 10 mg/kg

Application Route : Oral

Exposure time : 28-day

Dose : 0,5 - 60 mg/kg/day

Aspiration toxicity

Not classified based on available information.

Components:

Eprinomectin:

No data available



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Further information

Components: Eprinomectin:

Remarks : Neurotoxic effect.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Eprinomectin:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.37 mg/l

Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 1.2 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.00045 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

The value is given in analogy to the following substances: Avermectin A1a, 4"-(acetylamino)-5-O-demethyl-4"-deoxy-,

(4"R)-

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (algae)): 3.4 mg/l

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

Remarks: No data available

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.000028 mg/l

End point: reproduction rate

Method: OECD Test Guideline 211

Toxicity to microorganisms : Remarks: No data available

Toxicity to soil dwelling or-

ganisms

NOEC (Eisenia fetida (earthworms)): 19 mg/kg

Method: OECD Test Guideline 222

Sediment toxicity : NOEC (Chironomus riparius (Midge larvae)): 0.00034 mg/l

Method: OECD Test Guideline 218

Persistence and degradability

Product:

Biodegradability : Result: No data available



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Components:

Eprinomectin:

Biodegradability : Inoculum: Soil

Result: Persistent substance with a half life of more than 60

days.

Method: OECD Test Guideline 307

Inoculum: Sediment

Result: Persistent substance with a half life of more than 60

days.

Method: OECD Test Guideline 308

Bioaccumulative potential

Product:

Bioaccumulation : Remarks: No data available

Components:

Eprinomectin:

Bioaccumulation : Remarks: An appreciable bioaccumulation potential is to be

expected (log P(o/w) > 3).

Species: Fish

Method: OECD Test Guideline 305 Remarks: Does not bioaccumulate.

Partition coefficient: n-

octanol/water

Pow: 5.4

Mobility in soil

Product:

Distribution among environ-

mental compartments

Remarks: No data available

Components:

Eprinomectin:

Distribution among environ-

mental compartments

Medium: Soil Koc: 1000

Kd: 15.7

Method: Adsorption/Desorption

Medium: Soil Koc: 9208 Kd: 133.5

Method: Adsorption/Desorption



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Other adverse effects

Product:

Ozone-Depletion Potential Regulation: 40 CFR Protection of Environment; Part 82 Pro-

tection 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).

Components:

Eprinomectin:

Results of PBT and vPvB

assessment

Persistent and Toxic

PBT substance

Additional ecological infor-

mation

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Dispose of in accordance with local regulations.

Contaminated packaging Packs that cannot be cleaned should be disposed of in the

same manner as the contents.

Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

UN/ID No. UN 3082

Proper shipping name Environmentally hazardous substance, liquid, n.o.s.

(Eprinomectin)

9 Class Packing group Ш

Miscellaneous Labels

Packing instruction (cargo

aircraft)

Packing instruction (passen-

964

964

ger aircraft)

Environmentally hazardous yes

IMDG-Code

UN number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.



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(Eprinomectin)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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

UN/ID/NA number : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Eprinomectin)

Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171

Marine pollutant : yes

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity

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 112 (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).



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This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI 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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Decanoic acid, mixed diesters with octanoic acid and propylene glycol 68583-51-7

Maine Chemicals of High Concern

This product does not contain any chemicals that are listed as Maine Chemicals of High Concern.

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The components of this product are reported in the following inventories:

TCSI : Not in compliance with the inventory

TSCA : Substance(s) not listed on TSCA inventory

AICS : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Eprinomectin

Decanoic acid, mixed diesters with octanoic acid and propyl-

ene glycol

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory



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IECSC : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

TSCA list

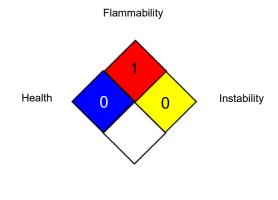
No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



Special hazard

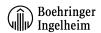
HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification 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; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Indus-



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trial 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ -Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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

Vertical lines in the left hand margin indicate an amendment from the previous version.

Sources of key data used to

compile the Safety Data

Sheet

The specifications are based on own tests and/or literature

data.

Revision Date : 06/10/2020

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.

US / EN