

# Nilotinib hydrochloride monohydrate

## Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Dáta eisiúna: 03/04/2023 Dáta athbhreithnithe: 16/05/2023 Supersedes version of: 03/04/2023 Leagan: 2.0

### CUID 1: Sainaitheant na substainte / an mheascáin agus na cuideachta / an ghnóthais

#### 1.1. Sainaitheantóir táirge

Foirm an táirge	: Substance
Substance name	: Nilotinib hydrochloride monohydrate
Chemical name	: 4-Methyl-N-[3-(4-methyl-1H-imidazol-1-yl)-5-(trifluoromethyl)phenyl]-3-[(4-pyridin-3-yl)pyrimidin-2-yl]amino]benzamide hydrochloride monohydrate
Cód an táirge	: 201800028

#### 1.2. Úsáidí ábhartha sainaitheanta na substainte nó an mheascáin agus úsáidí atá dímholta

##### 1.2.1. Úsáidí sainaitheanta ábhartha

Príomhchatagóir úsáide	: The product is intended for research, analysis and scientific education.
Úsáid na substainte / an mheascáin	: For professional use only
Function or use category	: Laboratory chemicals

##### 1.2.2. Úsáidí dímholta

Restrictions on use	: Do not use : Ingestion, Inhalation, Dermal
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#### 1.3. Sonraí um sholáthraí na bileoige sonraí sábháilteachta

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe 7, Allée Kastner, CS30026  
F- 67081 Strasbourg  
France  
T +33(0)388412035 - F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu) - [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Uimhir ghutháin éigeandála

Uimhir éigeandála	: +33(0)390215608
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### CUID 2: Aithint guaiseacha

#### 2.1. Aicmiú na substainte nó an mheascáin

##### Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]

Tocsaineacht atáirgeach, Catagóir 2	H361	
Tocsaineacht sain-spricorgáin – Athnochtadh, Catagóir 1	H372	
Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 1	H410	(M=10)

Full text of H- and EUH-statements: see section 16

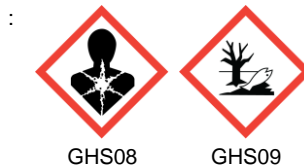
##### Éifeachtaí díobhálacha fisiceimiceacha, um shláinte an duine agus um an comhshaol

Expert judgement and weight of evidence determination.

#### 2.2. Eilimintí lipéid

##### Lipéadú de réir Rialachán (CE) Uimh. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS08

GHS09

Signal word (CLP)	: Contúirt
Hazard statements (CLP)	: H361 - Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn. H372 - Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh. H410 - An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.
Ráitis réamhchúraim (CLP)	: P201 - Faigh treoracha speisialta roimh úsáid. P202 - Ná láimhsigh go dtí go léifear agus go dtuigfear gach ráiteas réamhchúraim

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sábháilteachta.

P260 - Ná hanálaigh deannach/múch/gás/ceo/gala/sprae.

P264 - Nigh ... go lánchúramach tar éis lámhsithe.

P270 - Ná hith, ná hól agus ná caitear tobac agus an táirge seo á úsáid.

P273 - Ná scaoiltear amach sa chomhshaol.

P280 - Caith lámhainní cosanta/éadaí cosanta/cosaint súile/cosaint aghaidhe.

P314 - Faigh comhairle/cúram liachta má bhraitheann tú tinn.

P391 - Bailigh doirteadh.

P405 - Stóráil faoi ghlas.

P501 - Diúscair an t-ábhar/an coimeádán i ...

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

Hazard pictograms (CLP)



GHS08

### 2.3. Guaiseacha eile

Níl aon fhaisnéis bhreise ar fáil

## CUID 3: Comhdhéanamh / faisnéis faoi chomhábhair

### 3.1. Substaint

Ainm	Sainitheantóir táirge		Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]
4-Methyl-N-[3-(4-methyl-1H-imidazol-1-yl)-5-(trifluoromethyl)phenyl]-3-[(4-pyridin-3-ylpyrimidin-2-yl)amino]benzamide hydrochloride monohydrate	-	≤ 100	Repr. 2, H361 STOT RE 1, H372 Aquatic Chronic 1, H410 (M=10)

Full text of H- and EUH-statements: see section 16

### 3.2. Meascán

Ní bhaineann le hábhar

## CUID 4: Bearta garchabhrach

### 4.1. Cur síos ar na bearta garchabhrach

Bearta garchabhrach tar éis ionanáilaithe	: Move to fresh air. Allow affected person to breathe fresh air.
Bearta garchabhrach tar éis teagmhála leis an gcráiceann	: Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent.
Bearta garchabhrach tar éis teagmhála leis an tsúil	: Rinse with water while holding the eyes wide open.
Bearta garchabhrach tar éis iontógála	: Sruthlaítear an béal. Specific medical surveillance. Prolonged medical observation may be indicated.

### 4.2. Na siomptóim agus na héifeachtaí is tábhachtaí, idir shiomptóim ghéarmhíochaine agus shiomptóim mhoillithe

Symptoms/effects	: Delayed adverse effects possible.
Siomptóim/gortuithe tar éis ionanáilaithe	: Insufficient data available.
Siomptóim/gortuithe tar éis teagmhála leis an gcráiceann	: Insufficient data available.
Siomptóim/gortuithe tar éis teagmhála leis an tsúil	: Insufficient data available.
Siomptóim/gortuithe tar éis iontógála	: Symptoms may include dizziness, headache, nausea and loss of coordination.

### 4.3. Léiriú ar aon chóir leighis láithreach agus aon chóir speisialta atá ag teastáil

Faigh comhairle/cúram liachta. If possible show this sheet, if not available show packaging or label. Active substance. Pharmaceutical.

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### CUID 5: Bearta comhrac dóiteáin

#### 5.1. Meáin múchta

Meáin oiriúnacha um múchadh : Extinguishing blanket.

#### 5.2. Guaiseacha speisialta a eascraíonn as an tsubstaint nó as an meascán

Guais dóiteáin : See Heading 2.2.

#### 5.3. Comhairle do chomhraiceoirí dóiteáin

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

### CUID 6: Bearta i gcás scaoileadh de thaisme

#### 6.1. Réamhchúirí pearsanta, trealamh cosanta agus nósanna imeachta éigeandála

Bearta ginearálta : Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.

##### 6.1.1. Do phearsanra neamh-éigeandála

Emergency procedures : Wear suitable protective clothing, gloves and eye or face protection.

##### 6.1.2. D'fhreagróirí éigeandála

Níl aon fhaisnéis bhreise ar fáil

#### 6.2. Réamhchúirí comhshaoil

Níl aon fhaisnéis bhreise ar fáil

#### 6.3. Modhanna agus ábhar maidir le coimeád agus glanadh suas

Modhanna um ghlanadh : Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with : Sodium hypochlorite solution.

#### 6.4. Tagairt do chodanna eile

Níl aon fhaisnéis bhreise ar fáil

### CUID 7: Láimhseáil agus stóráil

#### 7.1. Réamhchúirí maidir le láimhseáil shábháilte

Additional hazards when processed : The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.

Réamhchúirí maidir le láimhseáil shábháilte : Material should be handled with caution. Avoid any direct contact with the product. Material should be handled in a laboratory hood whenever possible.

Bearta sláinteachais : Handle in accordance with good industrial hygiene and safety procedures.

#### 7.2. Coinníollacha stórála sábháilte, lena n-áirítear aon neamhlú

Technical measures : Comply with applicable regulations.

Coinníollacha stórála : Stóráil faoi ghlas.

#### 7.3. Úsáid shonrach deiridh nó úsáid sonracha deiridh

See Heading 1.

### CUID 8: Rialuithe nochtta / cosaint phearsanta

#### 8.1. Paraiméadair rialaithe

##### 8.1.1 National occupational exposure and biological limit values

Níl aon fhaisnéis bhreise ar fáil

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### 8.1.2. Recommended monitoring procedures

Níl aon fhaisnéis bhreise ar fáil

### 8.1.3. Air contaminants formed

Níl aon fhaisnéis bhreise ar fáil

### 8.1.4. DNEL and PNEC

Níl aon fhaisnéis bhreise ar fáil

### 8.1.5. Control banding

Níl aon fhaisnéis bhreise ar fáil

## 8.2. Rialuithe nochta

### 8.2.1. Appropriate engineering controls

#### Rialuithe iomchuí innealtóireachta:

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Cosaint súl:

Safety glasses. DIN EN 166

#### 8.2.2.2. Skin protection

##### Cosaint chraicinn agus choirp:

Use chemically protective clothing. DIN EN 13034

##### Cosaint lámha:

Chemically resistant protective gloves. ISO 374-1

#### 8.2.2.3. Respiratory protection

##### Cosaint riospráide:

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

#### 8.2.2.4. Thermal hazards

Níl aon fhaisnéis bhreise ar fáil

### 8.2.3. Environmental exposure controls

Níl aon fhaisnéis bhreise ar fáil

## CUID 9: Airíonna fisiceacha agus ceimiceacha

### 9.1. Faisnéis bunaithe ar bhunairíonna fisiceacha agus ceimiceacha

Staid fhisiceach	: Solid
Dath	: Not available
Dealramh	: Crystalline powder.
Boladh	: Ní bhaineann le hábhar.
Tairseach bolaidh	: Not available
Leáphointe	: Not available
Reophointe	: Not available
Fiuchphointe	: Not available
Inadhainteacht	: Not available
Teorainneacha pléascacha	: Ní bhaineann le hábhar
Lower explosion limit	: Ní bhaineann le hábhar
Upper explosion limit	: Ní bhaineann le hábhar
Splancphointe	: Ní bhaineann le hábhar
Teocht uath-adhainte	: Ní bhaineann le hábhar
Teocht dianscaoilte	: Not available
pH	: Not available
pH solution	: Not available

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Slaodacht, cinéimiteach	: Ní bhaineann le hábhar
Intuaslagthacht	: Uisce: < 0.1 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Galbhrú	: Not available
Vapour pressure at 50°C	: Not available
Dlús	: Not available
Dlús coibhneasta	: Not available
Galdlús coibhneasta ag 20°C	: Ní bhaineann le hábhar
Particle size	: Not available

### 9.2. Faisnéis eile

#### 9.2.1. Information with regard to physical hazard classes

Níl aon fhaisnéis bhreise ar fáil

#### 9.2.2. Other safety characteristics

Níl aon fhaisnéis bhreise ar fáil

## CUID 10: Cobhsaíocht agus imoibríocht

### 10.1. Imoibríocht

Stable under normal conditions.

### 10.2. Cobhsaíocht cheimiceach

Níl aon fhaisnéis bhreise ar fáil

### 10.3. D'fhéadfadh a bheith ina chúis le fhrithghníomhartha guaiseacha

Níl aon fhaisnéis bhreise ar fáil

### 10.4. Coinníollacha lena seachaint

Níl aon fhaisnéis bhreise ar fáil

### 10.5. Ábhair neamh-chomhoiriúnacha

None under normal use. See Section 7.

### 10.6. Táirgí dian-scaoilte guaiseacha

When heated to decomposition, emits dangerous fumes.

## CUID 11: Faisnéis thocsaineolaíoch

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

Acute toxicity (oral)	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

#### 4-Methyl-N-[3-(4-methyl-1H-imidazol-1-yl)-5-(trifluoromethyl)phenyl]-3-[(4-pyridin-3-yl)pyrimidin-2-yl]amino]benzamide hydrochloride monohydrate

LD50 ó bhéal francach	> 2000 mg/kg
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Creimeadh/greannú craicinn	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Damáiste/greannú tromchúiseach súl	: Not classified (Lack of data)
Íoghrú riospráide nó craicinn	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Só-ghineacht ghaiméite	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Carcanaigineacht	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Tocsaineacht atáirgthe	: Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn.
Tocsaineacht sain-spricorgáin (aon nochtadh amháin)	: Not classified (Lack of data)

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Tocsaineacht sain-spricorgáin (ilnochtadh) : Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh.  
Guais asúite : Not classified (Technical impossibility to obtain the data)

### 11.2. Information on other hazards

Níl aon fhaisnéis bhreise ar fáil

## CUID 12: Faisnéis éiceolaíochta

### 12.1. Tocsaineacht

Éiceolaíocht - ginearálta : Hazardous waste. Use suitable disposal containers.  
Guaiseach don chomhshaoil uisceach, ghearrthéarmach (géarghuais) : Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)  
Guaiseach don chomhshaoil uisceach, fadtéarmach (guais ainsealach) : An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.  
Not rapidly degradable

4-Methyl-N-[3-(4-methyl-1H-imidazol-1-yl)-5-(trifluoromethyl)phenyl]-3-[(4-pyridin-3-yl)pyrimidin-2-yl]amino]benzamide hydrochloride monohydrate	
LC50 - Fish [1]	> 100 mg/l (96 Hours, Brachydanio rerio (zebra-fish)) (92/69/EEC (L383) C.1)
EC50 - Crustacea [1]	> 100 mg/l (48 Hours, Daphnia magna (Water flea)) (92/69/EEC (L383) C.2)
ErC50 algae	> 0.016 mg/l (72 Hours, Pseudokirchneriella subcapitata/Selenastrum capricornutum (Green algae)) (92/69/EEC (L383) C.3)
NOEC chronic fish	> 0.013 mg/l (35 days, Brachydanio rerio (zebra-fish)) (OECD 210 method)
NOEC chronic crustacea	0.0127 mg/l (21 days, Daphnia magna (Water flea)) (OECD 211 method)
NOEC chronic algae	0.008 mg/l (72 Hours, Pseudokirchneriella subcapitata/Selenastrum capricornutum (Green algae)) (92/69/EEC (L383) C.3)

### 12.2. Inchoimeádachas agus díghrádaitheacht

Níl aon fhaisnéis bhreise ar fáil

### 12.3. Acmhainneacht bhithbhailitheach

Níl aon fhaisnéis bhreise ar fáil

### 12.4. Soghluaisteacht san ithir

Níl aon fhaisnéis bhreise ar fáil

### 12.5. Torthaí an mheasúnaithe PBT agus vPvB

Níl aon fhaisnéis bhreise ar fáil

### 12.6. Endocrine disrupting properties

Níl aon fhaisnéis bhreise ar fáil

### 12.7. Éifeachtaí díobhálacha eile

Níl aon fhaisnéis bhreise ar fáil

## CUID 13: Breithnithe diúscartha

### 13.1. Modhanna cóireála dramhaíola

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.




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### CUID 14: Faisnéis Iompair

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
UN 3077	UN 3077	UN 3077
<b>14.2. Ainm seolta ceart UN</b>		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
<b>Transport document description</b>		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
<b>14.3. Aicme nó aicmí guaise iompair</b>		
9	9	9
		
<b>14.4. Grúpa pacála</b>		
III	III	III
<b>14.5. Guaiseacha comhshaoil</b>		
Contúirteach don chomhshaoil: Tá	Contúirteach don chomhshaoil: Tá Truailleán mara: Tá	Contúirteach don chomhshaoil: Tá

### 14.6. Réamhchúraimí speisialta don úsáideoir

#### Iompar ar talamh

Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V13
Special provisions for carriage - Bulk (ADR)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	:



Tunnel restriction code (ADR) : -

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### Iompar ar muir

Special provision (IMDG)	: 274, 335, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP02, P002
Packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: BK1, BK2, BK3, T1
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-F
Stowage category (IMDG)	: A
Stowage and handling (IMDG)	: SW23

### Aeriompar

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y956
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 956
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197, A215
ERG code (IATA)	: 9L

## 14.7. Maritime transport in bulk according to IMO instruments

Ní bhaineann le hábhar

## CUID 15: Faisnéis rialála

### 15.1. Rialacháin/reachtaíocht sábháilteacht, sláinte agus chomhshaoil a bhaineann go sonrach leis an tsubstaint nó an meascán

#### 15.1.1. Rialacháin de chuid an AE

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Ní bhaineann le hábhar

##### POP Regulation (Persistent Organic Pollutants)

Ní bhaineann le hábhar

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. Rialacháin náisiúnta

Níl aon fhaisnéis bhreise ar fáil



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### 15.2. Measúnú sábháilteachta ceimicí

Níl aon fhaisnéis bhreise ar fáil

### CUID 16: Faisnéis eile

Léiriú ar na hathruithe			
Cuid	Changed item	Change	Comments
2.1	Aicmiú na substainte nó an mheascáin	Modified	
2.2	Eilimintí lipéid	Modified	
11.1	Reason for no classification	Modified	
11.1	ATE CLP (oral)	Modified	
12.1	Reason for no classification	Modified	
14	Faisnéis Iompair	Modified	

Full text of H- and EUH-statements:	
Aquatic Chronic 1	Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 1
H361	Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn.
H372	Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh.
H410	An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.
Repr. 2	Tocsaineacht atáirgeach, Catagóir 2
STOT RE 1	Tocsaineacht sain-spríocorgáin – Athnochtadh, Catagóir 1

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.