

# NACERA® Blue X

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

Date of issue: 7/31/2017

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Supersedes: 3/31/2016

Version: 2.01

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Trade name : NACERA® Blue X

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

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : Combined with presintered NACERA® ceramic materials for adjustment of optical properties  
Medical device

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

DOCERAM Medical Ceramics GmbH  
Heßlingsweg 65-67  
44309 Dortmund - Germany  
T +49-231-92 56 68-0 - F +49-231-92 56 68-60

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Emergency number : National Health Service (NHS)  
24 hour national number consumer  
England and Scotland: 111  
Wales: 0845 46 47  
Northern Ireland: call your local General Practitioner  
  
Call 999 if there is a life-threatening incident.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Serious eye damage/eye irritation, Category H319

2

Hazardous to the aquatic environment — H400

Acute Hazard, Category 1

Hazardous to the aquatic environment — H410

Chronic Hazard, Category 1

Full text of hazard classes and H-statements : see section 16

#### Adverse physicochemical, human health and environmental effects

Causes serious eye irritation. Very toxic to aquatic life with long lasting effects.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

GHS09

Signal word (CLP) : Warning

Hazard statements (CLP) : H319 - Causes serious eye irritation  
H410 - Very toxic to aquatic life with long lasting effects

Precautionary statements (CLP) : P280 - Wear protective gloves, eye protection  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337+P313 - If eye irritation persists: Get medical advice/attention  
P391 - Collect spillage  
P501 - Dispose of contents/container to a hazardous or special waste collection point

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### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Comments : Aqueous solution of

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Yttrium(III)nitrate hexahydrate	(CAS-No.) 13494-98-9 (EC-No.) 233-802-6	50 - 70	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention. If possible show this sheet, if not available show packaging or label.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth out with water. Spit. Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after eye contact : Eye irritation.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Carbon dioxide. For a significant fire : Alcohol resistant foam. Water spray.

Unsuitable extinguishing media : Strong water jet.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released. Nitrogen oxides. Metal oxides.

### 5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

Other information : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes.

#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Notify authorities if product enters sewers or public waters. Avoid sub-soil penetration. Prevent entry to sewers and public waters.

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### 6.3. Methods and material for containment and cleaning up

- For containment : Collect spillage.
- Methods for cleaning up : Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
- Other information : Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment.
- Hygiene measures : Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Store at room temperature. Keep cool. Protect against frost. Keep container tightly closed.
- Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

#### Hand protection:

In case of repeated or prolonged contact wear gloves. EN 374. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

#### Eye protection:

Wear closed safety glasses. EN 166

#### Skin and body protection:

Wear suitable protective clothing

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. EN 143. EN 149. Short term exposure. Breathing apparatus with filter. P2.

#### Environmental exposure controls:

Avoid release to the environment.

#### Other information:

Do not breathe Aerosol. Do not eat and do not drink during use. Avoid contact with eyes. Always wash hands after handling the product.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

- Physical state : Liquid
- Colour : Blue.
- Odour : characteristic.
- Odour threshold : No data available
- pH : 2 - 4
- Relative evaporation rate (butylacetate=1) : No data available

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Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not self-igniting
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Water: completely miscible
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing. Test O.1 Test for oxidizing solids Y(NO3)3.
Explosive limits	: Not applicable

### 9.2. Other information

Bulk density : 1510 kg/m<sup>3</sup>

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity (oral)	: Oral: Not classified. (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

ATE CLP (oral)	2500 mg/kg bodyweight
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<b>Yttrium(III)nitrate hexahydrate (13494-98-9)</b>	
LD50 oral rat	1650 mg/kg bodyweight (OECD 401 method)

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 2 - 4
Serious eye damage/irritation	: Causes serious eye irritation. pH: 2 - 4
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)

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Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : Very toxic to aquatic life with long lasting effects.  
Acute aquatic toxicity : Very toxic to aquatic life.  
Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

#### Yttrium(III)nitrate hexahydrate (13494-98-9)

EC50 Daphnia 1	> 100 mg/l (24 h; Daphnia magna; EU Method C.2) After 24 hours a decrease of dissolved Y to <= 1 mg Y/L (detection limit) was observed. The initial dissolved Y concentration was 23 mg Y/L. - Y was present in the precipitate at the bottom of the vessels.
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#### 12.2. Persistence and degradability

No additional information available

#### 12.3. Bioaccumulative potential

No additional information available

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

##### NACERA® Blue X

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

#### 12.6. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.

HP Code : HP4 - "Irritant — skin irritation and eye damage:" waste which on application can cause skin irritation or damage to the eye.  
HP14 - "Ecotoxic:" waste which presents or may present immediate or delayed risks for one or more sectors of the environment

### SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number</b>				
3082	3082	3082	3082	3082
<b>14.2. UN proper shipping name</b>				
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Yttrium(III)nitrate hexahydrate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Yttrium(III)nitrate hexahydrate)	Environmentally hazardous substance, liquid, n.o.s. (Yttrium(III)nitrate hexahydrate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Yttrium(III)nitrate hexahydrate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Yttrium(III)nitrate hexahydrate)
<b>Transport document description</b>				
UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Yttrium(III)nitrate hexahydrate), 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Yttrium(III)nitrate hexahydrate), 9, III, MARINE POLLUTANT	UN 3082 Environmentally hazardous substance, liquid, n.o.s. (Yttrium(III)nitrate hexahydrate), 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Yttrium(III)nitrate hexahydrate), 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Yttrium(III)nitrate hexahydrate), 9, III
<b>14.3. Transport hazard class(es)</b>				
9	9	9	9	9

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ADR	IMDG	IATA	ADN	RID
<b>14.4. Packing group</b>				
III	III	III	III	III
<b>14.5. Environmental hazards</b>				
Dangerous for the environment : Yes	Dangerous for the environment : Yes Marine pollutant : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available				

### 14.6. Special precautions for user

#### - Overland transport

Classification code (ADR) : M6  
Special provisions (ADR) : 274, 335, 375, 601  
Limited quantities (ADR) : 5I  
Excepted quantities (ADR) : E1  
Transport category (ADR) : 3  
Hazard identification number (Kemler No.) : 90  
Orange plates :



#### - Transport by sea

Special provisions (IMDG) : 274, 335, 969  
Limited quantities (IMDG) : 5 L  
Excepted quantities (IMDG) : E1  
EmS-No. (Fire) : F-A  
EmS-No. (Spillage) : S-F

#### - Air transport

PCA Excepted quantities (IATA) : E1  
PCA Limited quantities (IATA) : Y964  
PCA limited quantity max net quantity (IATA) : 30kgG  
PCA packing instructions (IATA) : 964  
PCA max net quantity (IATA) : 450L  
CAO max net quantity (IATA) : 450L  
Special provisions (IATA) : A97, A158, A197

#### - Inland waterway transport

Classification code (ADN) : M6  
Special provisions (ADN) : 274, 335, 375, 601  
Limited quantities (ADN) : 5 L  
Excepted quantities (ADN) : E1  
Carriage permitted (ADN) : T

#### - Rail transport

Classification code (RID) : M6  
Special provisions (RID) : 274, 335, 375, 601  
Limited quantities (RID) : 5L  
Excepted quantities (RID) : E1  
Transport category (RID) : 3  
Hazard identification number (RID) : 90

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

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### SECTION 15: Regulatory information

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

##### 15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	NACERA® Blue X
3(c) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1	NACERA® Blue X

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Directive 2012/18/EU (SEVESO III) : E1 Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

Indication of changes:

General revision.

Section	Changed item	Change	Comments
9.1	pH	Modified	

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources : ECHA (European Chemicals Agency). Information provided by the manufacturer.

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Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark. 3 64347 Griesheim  
Postfach 1451 64345 Griesheim  
Germany

Phone: +49 6155-8981-400 Fax: +49 6155 8981-500  
Safety Data Sheet Service: +49 6155 8981-522

Contact person : Dr. Johann Klassen

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed
H319	Causes serious eye irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Eye Irrit. 2	H319	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

KFT SDS EU 00

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*