SAFETY DATA SHEET

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: Rox Factor IX
Product Number: 900020

Intended Use

For In Vitro Diagnostic Use (Only in EU)
For In Vitro Research Use (Outside EU)

Company Identification

Rossix AB
Taljegardsgatan 3B
S-43153 Molndal
Sweden

Tel: +46 (0)31 706 8965
Fax: +46 (0)31 706 8966
info@rossix.com
www.rossix.com

This document contains the Safety Data Sheets for the individual components in the Rox Factor IX kit

<table>
<thead>
<tr>
<th>P/N</th>
<th>Mixture Name</th>
<th>Mixture classification</th>
<th>Kit configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>9010</td>
<td>Reagent A</td>
<td>Safety Data Sheet</td>
<td>Issued March 12, 2018 version 1.0</td>
</tr>
<tr>
<td>9020</td>
<td>Reagent B</td>
<td>Safety Data Sheet</td>
<td>Issued March 12, 2018 version 1.0</td>
</tr>
<tr>
<td>9050</td>
<td>FIX Diluent Buffer</td>
<td>Safety Data Sheet</td>
<td>Issued March 12, 2018 version 1.0</td>
</tr>
<tr>
<td>9080</td>
<td>FXa Substrate</td>
<td>Safety Data Sheet</td>
<td>Issued March 12, 2018 version 1.0</td>
</tr>
</tbody>
</table>

These Safety Data Sheets replaces the Safety Data Sheet Rox Factor IX Issued Nov 07, 2016

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

<table>
<thead>
<tr>
<th>P/N</th>
<th>Mixture Name</th>
<th>Mixture classification</th>
<th>Kit configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>9010</td>
<td>Reagent A</td>
<td>Not classified</td>
<td>2 vials (lyophilized powder, &lt; 0.2 g per vial, to be reconstituted in 1.4 ml Aq)</td>
</tr>
<tr>
<td>9020</td>
<td>Reagent B</td>
<td>Not classified</td>
<td>2 vials (lyophilized powder, &lt; 0.2 g per vial, to be reconstituted in 8.0 ml Aq)</td>
</tr>
<tr>
<td>9050</td>
<td>FIX Diluent Buffer</td>
<td>Not classified</td>
<td>1 x 20 mL</td>
</tr>
<tr>
<td>9080</td>
<td>FXa Substrate</td>
<td>Not classified</td>
<td>1 x 6 mL</td>
</tr>
</tbody>
</table>

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user’s responsibility for the product’s safe use, the product’s suitability for the intended use and the product’s safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers.
SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
   Trade name: Reagent A (part of 900020 Rox Factor IX kit)
   Article number: 9010

1.2. Relevant identified uses of the substance or mixture and uses advised against
   Identified uses:
   - Laboratory chemicals
   - In Vitro Diagnostic Use – Only in EU
   - In Vitro Research Use – Outside EU

1.3. Details of the supplier of the safety data sheet
   Company: Rossix AB
   Taljegårdsgatan 3B
   43153 Mölndal
   Sweden
   Telephone: +46 (0)31 7068965
   E-mail: info@rossix.com
   Website: www.rossix.com

1.4. Emergency telephone number
   Acute cases: Call 112, request poison information.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
   Upon assessment, this mixture is not classified as hazardous according to 1272/2008.

2.2. Label elements
   Hazard pictogram: Not applicable
   Signal word: Not applicable
   Hazard statement: Not applicable

2.3. Other hazards
   This product contains purified human coagulation factors isolated from human plasma. Each donor unit used in the preparation has tested negative (using FDA approved methods) for the presence of Hepatitis B surface antigen and antibodies against Hepatitis C, HIV 1 and 2.
   This product contains bovine serum albumin (BSA). All donor animals are from BSE- and TSE-free livestock. Donor animals have been subjected to veterinary examination before and after donation, determining that the animals are indeed free of infectious materials.
   Although this product has been thoroughly tested, biological materials should always be handled as potentially infectious as a precaution.

SECTION 3: Composition/information on ingredients

3.2. Mixtures
   Note that the table shows known hazards of the ingredients in pure form. These hazards are reduced or eliminated when mixed or diluted, see Section 16d.

<table>
<thead>
<tr>
<th>Constituent</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALCIUM CHLORIDE DIHYDRATE</td>
<td></td>
<td>9 %</td>
</tr>
<tr>
<td>CAS No: 10035-04-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC No: 233-140-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Index No: 017-013-00-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>REACH: 01-2119494219-28</td>
<td>Eye Irrit 2; H319</td>
<td></td>
</tr>
</tbody>
</table>

Explanations to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in normal font. Text in italics are specifications and/or complements used in the calculation of the classification of this mixture,
SECTION 4: First aid measures

4.1. Description of first aid measures
Generally
In case of concern, or if symptoms occur, call a doctor/physician.

Upon breathing in
Fresh air and rest. If symptoms persist seek medical advice.

Upon eye contact
For safety reasons, flush eyes with water; If symptoms occur, seek medical advice.

Upon skin contact
Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

Upon ingestion
Rinse mouth out thoroughly first with water, then SPIT OUT the rinse water. Drink at least half a litre of water and seek medical advice. DO NOT INDUCE VOMITING.

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

Upon eye contact
Splashes in eyes may cause burning pain.
Irritation may occur due to mechanical abrasion.

Upon skin contact
Prolonged contact may cause skin irritation.

4.3. Indication of any immediate medical attention and special treatment needed
Symptomatic treatment.
Upon contact with a doctor, make sure to have the label or this safety data sheet with you.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media
Extinguish with water mist, powder, carbon dioxide or alcohol-resistant foam.

5.2. Special hazards arising from the substance or mixture
Gases detrimental to health can be spread in case of fire.

5.3. Advice for fire-fighters
Protective measures should be taken regarding other material at the site of the fire.
In case of fire use a respirator mask.
Wear full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Avoid inhalation and exposure to skin and eyes.
Keep unauthorized and unprotected people at a safe distance.
Use recommended safety equipment, see section 8.
Ensure good ventilation.

6.2. Environmental precautions
Avoid release to drains, soil or watercourses.

6.3. Methods and material for containment and cleaning up
Carefully collect dry product without dust formation and dispose as waste.
Minor spills can be dried up or flushed away with water.

6.4. Reference to other sections
See section 8 and 13 for personal protection equipment and disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Avoid spillage, inhalation and contact with eyes and skin.
Do not eat, drink or smoke in premises where this product is handled.
Use recommended safety equipment, see section 8.

7.2. Conditions for safe storage, including any incompatibilities
The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.
Store separately from food and animal fodder, incl. utensils or surfaces which have been in contact with these things.
Always use sealed and visibly labeled packages.
Store in a dry place at 2 - 8 °C.
The product is stable until the expiration date when stored under recommended conditions.

7.3. Specific end uses
See identified uses in Section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters
8.1.1. National limit values
DUST, RESPIRABLE

United Kingdoms (EH40/2005)
Time-weighted-average exposure limit (TWA) 4 mg/m³

DUST, INHALABLE

United Kingdoms (EH40/2005)
Time-weighted-average exposure limit (TWA) 10 mg/m³

DNEL
No data available.
PNEC
No data available.

8.2. Exposure controls
To prevent occupational risks the health hazards for this product or any of the ingredients should be taken into account (see sections 2, 3 and 11), according to EU Directive 89/391 and 98/24 and national jurisdiction for occupational risks.

8.2.1. Appropriate engineering controls
Handle in premises which have modern ventilation standards.
Eye-rinsing facilities shall be available at the workplace.

Eye/face protection
Use dust protective glasses when handling may create dust.

Skin protection
Use suitable protective clothing.
During normal use hand protection is not necessary, but it is recommended during repeated/prolonged contact with the product. Recommended glove material: nitrile, butyl or rubber.

Respiratory protection
Dust filter (EN 143) may be necessary when performing dust forming work.

8.2.3. Environmental exposure controls
Work with the product should take place in such a way that the product does not get into drains, waterways, soil and air.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance
Form: lyophilised powder.
b) Odour
Not indicated
c) Odour threshold
Not indicated
d) pH
Not indicated
e) Melting point/freezing point
Not indicated
f) Initial boiling point and boiling range
Not indicated
g) Flash point
Not indicated
h) Evaporation rate
Not indicated
i) Flammability (solid, gas)
Not applicable
j) Upper/lower flammability or explosive limits
Not indicated
k) Vapour pressure
Not indicated
l) Vapour density
Not indicated
m) Relative density
Not indicated
n) Solubility
Solubility in water: Soluble
o) Partition coefficient: n-octanol/water
Not applicable
p) Auto-ignition temperature
Not indicated
q) Decomposition temperature
Not indicated
r) Viscosity
Not indicated
s) Explosive properties
Not applicable
t) Oxidising properties
Not applicable
SECTION 10: Stability and reactivity

10.1. Reactivity
The product contains no substances which can lead to hazardous reactions at normal use.

10.2. Chemical stability
The product is stable at normal storage and handling conditions.

10.3. Possibility of hazardous reactions
No hazardous reactions known during normal use.

10.4. Conditions to avoid
None in particular.

10.5. Incompatible materials
None known.

10.6. Hazardous decomposition products
Does not decompose to hazardous substances.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Not indicated.

Acute toxicity
The product is not classified as acute toxic.

CALCIUM CHLORIDE DIHYDRATE
LD50 rabbit 24h: 2630 mg/kg Dermally
LD50 rat 24h: 1000 mg/kg Orally

Skin corrosion/irritation
Can cause skin irritation after repeated or prolonged contact.

Serious eye damage/irritation
Eye contact may cause burning pain or irritation. Dust may cause mechanical abrasion of the cornea.

Respiratory or skin sensitisation
Hypersensitive reactions cannot be ruled out for persons who are overtly sensitive.

Germ cell mutagenicity
No mutagenic effects have been reported for the substance in this mixture.

Carcinogenicity
No carcinogenic effects have been reported for the substances in this product.

Reproductive toxicity
No toxic effects to reproduction have been reported for the substances in this product.

STOT-single exposure
No known hazards for occasional exposure.

STOT-repeated exposure
No known hazards for repeated exposure.

Aspiration hazard
The product is not classified as being toxic for aspiration.

SECTION 12: Ecological information

12.1. Toxicity
Avoid larger spills directly in soil, water and drains. No ecological damage is known or expected in the event of normal use.

CALCIUM CHLORIDE DIHYDRATE
LC50 Bluegill (Lepomis macrochirus) 96h: 10650 mg/l
EC50 Freshwater water flea (Daphnia magna) 48 h: 144 mg/l
IC50 Algae 72h: 3130 mg/l

12.2. Persistence and degradability
The product degrades easily in the natural environment.

12.3. Bioaccumulative potential
Neither this product, nor its contents, accumulates in nature.

12.4. Mobility in soil
The product is miscible with water and is therefore variable in soil and water.
12.5. Results of PBT and vPvB assessment
The criteria for PBT and vPvB does not apply to inorganic substances.

12.6. Other adverse effects
No known effects or hazards.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Waste handling of the product
Avoid discharge of undiluted product into sewers.
The product is not classified as hazardous waste.
Observe local regulations.
See also national waste regulations.
Classification according to 2006/12
Recommended LoW-code: 18 01 07 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transport information
Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

14.1. UN number
Not classified as dangerous goods

14.2. UN proper shipping name
Not applicable

14.3. Transport hazard class(es)
Not applicable

14.4. Packing group
Not applicable

14.5. Environmental hazards
Not applicable

14.6. Special precautions for user
Not applicable

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Not applicable

14.8 Other transport information
Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Not indicated.

15.2. Chemical safety assessment
Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

SECTION 16: Other information

16a. Indication of where changes have been made to the previous version of the safety data sheet
Revisions of this document
This is the first version

16b. Legend to abbreviations and acronyms used in the safety data sheet
Full texts for Hazard Class and Category Code mentioned in section 3
Eye Irrit 2  Irritates eyes (Category 2)

Explanations of the abbreviations in Section 14
ADR  European Agreement concerning the International Transport of Dangerous Goods by Road
RID  Regulations concerning the International Transport of Dangerous Goods by Rail
IMDG  International Maritime Dangerous Goods Code
ICAO  International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)
IATA  The International Air Transport Association

16c. Key literature references and sources for data
Sources for data
Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex 1, as updated to 2018-03-12.
Where such data was not available, alternative documentation used to establish the official classification was used, e.g.
IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

**Full texts for Regulations mentioned in this Safety Data Sheet**

**1907/2006**

**2015/830**

**1272/2008**

**EH40/2005**
EH40/2005 Workplace exposure limits

**2006/12**
DIRECTIVE 2006/12/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2006 on waste

**1907/2006**

**16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification**

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

**16e. List of relevant hazard statements and/or precautionary statements**

**Full texts for hazard statements mentioned in section 3**

H319 Causes serious eye irritation

**16f. Advice on any training appropriate for workers to ensure protection of human health and the environment**

**Warning for misuse**

This product is not expected to cause severe harm to humans or the environment. The manufacturer, the distributor or the supplier are not responsible for adverse effects if the product is not handled in accordance with the directions for use.

**Other relevant information**

**Editorial information**

This material safety data sheet has been prepared and checked by KemRisk®, KemRisk Sweden AB, Platensgatan 8, SE-582 20 Linköping, Sweden, [www.kemrisk.se](http://www.kemrisk.se)
SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
   Trade name: Reagent B (part of 900020 Rox Factor IX kit)
   Article number: 9020

1.2. Relevant identified uses of the substance or mixture and uses advised against
   Identified uses:
   - Laboratory chemicals
   - In Vitro Diagnostic Use – Only in EU
   - In Vitro Research Use – Outside EU

1.3. Details of the supplier of the safety data sheet
   Company: Rossix AB
   Address: Taljegårdsgatan 3B, 43153 Mölndal, Sweden
   Telephone: +46 (0)31 7068965
   E-mail: info@rossix.com
   Website: www.rossix.com

1.4. Emergency telephone number
   Acute cases: Call 112, request poison information.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
   Upon assessment, this mixture is not classified as hazardous according to 1272/2008.

2.2. Label elements
   - Hazard pictogram: Not applicable
   - Signal word: Not applicable
   - Hazard statement: Not applicable

2.3. Other hazards
   This product contains purified human coagulation factors isolated from human plasma. Each donor unit used in the preparation has tested negative (using FDA approved methods) for the presence of Hepatitis B surface antigen and antibodies against Hepatitis C, HIV 1 and 2.
   This product contains bovine serum albumin (BSA). All donor animals are from BSE- and TSE-free livestock. Donor animals have been subjected to veterinary examination before and after donation, determining that the animals are indeed free of infectious materials.
   Although this product has been thoroughly tested, biological materials should always be handled as potentially infectious as a precaution.

SECTION 3: Composition/information on ingredients

3.2. Mixtures
   The product contains no substances, nor concentration levels thereof, that require marking or that need to be declared.

SECTION 4: First aid measures

4.1. Description of first aid measures
   Generally
   - In case of concern, or if symptoms occur, call a doctor/physician.
   Upon breathing in
   - Fresh air and rest. If symptoms persist seek medical advice.
   Upon eye contact
   - For safety reasons, flush eyes with water; If symptoms occur, seek medical advice.
   Upon skin contact
   - Wash skin with soap and water. If symptoms occur, seek medical advice.
Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

**Upon ingestion**
Rinse mouth out thoroughly first with water, then SPIT OUT the rinse water. Drink at least half a litre of water and seek medical advice. DO NOT INDUCE VOMITING.

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

**Upon eye contact**
Splashes in eyes may cause burning pain.
Irritation may occur due to mechanical abrasion.

**Upon skin contact**
Prolonged contact may cause skin irritation.

**4.3. Indication of any immediate medical attention and special treatment needed**
Symptomatic treatment.
Upon contact with a doctor, make sure to have the label or this safety data sheet with you.

**SECTION 5: Fire-fighting measures**

**5.1. Extinguishing media**
Extinguish with water mist, powder, carbon dioxide or alcoholresistant foam.

**5.2. Special hazards arising from the substance or mixture**
Gases detrimental to health can be spread in case of fire.

**5.3. Advice for fire-fighters**
Protective measures should be taken regarding other material at the site of the fire.
In case of fire use a respirator mask.
Wear full protective clothing.

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**
Avoid inhalation and exposure to skin and eyes.
Keep unauthorized and unprotected people at a safe distance.
Use recommended safety equipment, see section 8.
Ensure good ventilation.

**6.2. Environmental precautions**
Avoid release to drains, soil or watercourses.

**6.3. Methods and material for containment and cleaning up**
Carefully collect dry product without dust formation and dispose as waste.
Minor spills can be dried up or flushed away with water.

**6.4. Reference to other sections**
See section 8 and 13 for personal protection equipment and disposal considerations.

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**
Avoid spillage, inhalation and contact with eyes and skin.
Do not eat, drink or smoke in premises where this product is handled.
Use recommended safety equipment, see section 8.

**7.2. Conditions for safe storage, including any incompatibilities**
The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.
Store separately from food and animal fodder, incl. utensils or surfaces which have been in contact with these things.
Always use sealed and visibly labeled packages.
Store in a dry place at 2 - 8 °C.
The product is stable until the expiration date when stored under recommended conditions.

**7.3. Specific end uses**
See identified uses in Section 1.2.

**SECTION 8: Exposure controls/personal protection**

**8.1. Control parameters**

**8.1.1. National limit values**
All ingredients (cf. Section 3) lack occupational exposure limit values.

**DNEL**
No data available.
8.2. Exposure controls
To prevent occupational risks the health hazards for this product or any of the ingredients should be taken into account
(see sections 2, 3 and 11), according to EU Directive 89/391 and 98/24 and national jurisdiction for occupational risks.

8.2.1. Appropriate engineering controls
Handle in premises which have modern ventilation standards.
Eye-rinsing facilities shall be available at the workplace.

Eye/face protection
Use dust protective glasses when handling may create dust.

Skin protection
Use suitable protective clothing.
During normal use hand protection is not necessary, but it is recommended during repeated/prolonged contact with the
product. Recommended glove material: nitrile, butyl or rubber.

Respiratory protection
Dust filter (EN 143) may be necessary when performing dust forming work.

8.2.3. Environmental exposure controls
Work with the product should take place in such a way that the product does not get into drains, waterways, soil and air.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance Form: lyophilised powder.
b) Odour Not indicated
c) Odour threshold Not indicated
d) pH Not indicated
e) Melting point/freezing point Not indicated
f) Initial boiling point and boiling range Not indicated
g) Flash point Not indicated
h) Evaporation rate Not indicated
i) Flammability (solid, gas) Not applicable
j) Upper/lower flammability or explosive limits Not indicated
k) Vapour pressure Not indicated
l) Vapour density Not indicated
m) Relative density Not indicated
n) Solubility Solubility in water: Soluble
o) Partition coefficient: n-octanol/water Not applicable
p) Auto-ignition temperature Not indicated
q) Decomposition temperature Not indicated
r) Viscosity Not indicated
s) Explosive properties Not applicable
t) Oxidising properties Not applicable

9.2. Other information
No data available

SECTION 10: Stability and reactivity

10.1. Reactivity
The product contains no substances which can lead to hazardous reactions at normal use.

10.2. Chemical stability
The product is stable at normal storage and handling conditions.

10.3. Possibility of hazardous reactions
No hazardous reactions known during normal use.

10.4. Conditions to avoid
None in particular.

10.5. Incompatible materials
None known.

10.6. Hazardous decomposition products
Does not decompose to hazardous substances.

SECTION 11: Toxicological information
11.1. Information on toxicological effects

Not indicated.

Acute toxicity
The product is not classified as acute toxic.

Skin corrosion/irritation
Can cause skin irritation after repeated or prolonged contact.

Serious eye damage/irritation
Eye contact may cause burning pain or irritation.
Dust may cause mechanical abrasion of the cornea.

Respiratory or skin sensitisation
Hypersensitive reactions cannot be ruled out for persons who are overtly sensitive.

Germ cell mutagenicity
No mutagenic effects have been reported for the substance in this mixture.

Carcinogenicity
No carcinogenic effects have been reported for the substances in this product.

Reproductive toxicity
No toxic effects to reproduction have been reported for the substances in this mixture.

STOT-single exposure
No known hazards for occasional exposure.

STOT-repeated exposure
No known hazards for repeated exposure.

Aspiration hazard
The product is not classified as being toxic for aspiration.

SECTION 12: Ecological information

12.1. Toxicity
Avoid larger spills directly in soil, water and drains.
No ecological damage is known or expected in the event of normal use.

12.2. Persistence and degradability
The product degrades easily in the natural environment.

12.3. Bioaccumulative potential
Neither this product, nor its contents, accumulates in nature.

12.4. Mobility in soil
The product is miscible with water and is therefore variable in soil and water.

12.5. Results of PBT and vPvB assessment
The criteria for PBT and vPvB does not apply to inorganic substances.

12.6. Other adverse effects
No known effects or hazards.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Waste handling of the product
Avoid discharge of undiluted product into sewers.
The product is not classified as hazardous waste.
Observe local regulations.
See also national waste regulations.

Classification according to 2006/12
Recommended LoW-code: 18 01 07 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transport information

Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

14.1. UN number
Not classified as dangerous goods

14.2. UN proper shipping name
Not applicable

14.3. Transport hazard class(es)
Not applicable

14.4. Packing group
Not applicable
14.5. Environmental hazards
Not applicable

14.6. Special precautions for user
Not applicable

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Not applicable

14.8 Other transport information
Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Not indicated.

15.2. Chemical safety assessment
Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

SECTION 16: Other information

16a. Indication of where changes have been made to the previous version of the safety data sheet
This is the first version

16b. Legend to abbreviations and acronyms used in the safety data sheet

Explanations of the abbreviations in Section 14
ADR  European Agreement concerning the International Transport of Dangerous Goods by Road
RID  Regulations concerning the International Transport of Dangerous Goods by Rail
IMDG  International Maritime Dangerous Goods Code
ICAO  International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)
IATA  The International Air Transport Association

16c. Key literature references and sources for data

Sources for data
Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2018-03-12.
Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

Full texts for Regulations mentioned in this Safety Data Sheet
2006/12  DIRECTIVE 2006/12/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2006 on waste

16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification
Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.
16e. List of relevant hazard statements and/or precautionary statements

16f. Advice on any training appropriate for workers to ensure protection of human health and the environment

Warning for misuse
This product is not expected to cause severe harm to humans or the environment. The manufacturer, the distributor or the supplier are not responsible for adverse effects if the product is not handled in accordance with the directions for use.

Other relevant information

Editorial information
This material safety data sheet has been prepared and checked by KemRisk®, KemRisk Sweden AB, Platensgatan 8, SE-582 20 Linköping, Sweden, www.kemrisk.se
SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
   - Trade name: FIX Diluent Buffer
   - (part of 900020 Rox Factor IX kit)
   - Article number: 9050

1.2. Relevant identified uses of the substance or mixture and uses advised against
   - Identified uses: Laboratory chemicals
   - In Vitro Diagnostic Use – Only in EU
   - In Vitro Research Use – Outside EU

1.3. Details of the supplier of the safety data sheet
   - Company: Rossix AB
   - Taljegårdsgatan 3B
   - 43153 Mölndal
   - Sweden
   - Telephone: +46 (0)31 7068965
   - E-mail: info@rossix.com
   - Website: www.rossix.com

1.4. Emergency telephone number
   - Acute cases: Call 112, request poison information.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
   - Upon assessment, this mixture is not classified as hazardous according to 1272/2008.

2.2. Label elements
   - Hazard pictogram: Not applicable
   - Signal word: Not applicable
   - Hazard statement: Not applicable

2.3. Other hazards
   - This product does not contain any substances that are assessed to be a PBT or a vPvB
   - This product contains bovine serum albumin (BSA). All donor animals are from BSE- and TSE-free livestock. Donor animals have been subjected to veterinary examination before and after donation, determining that the animals are indeed free of infectious materials.
   - Although this product has been thoroughly tested, biological materials should always be handled as potentially infectious as a precaution.

SECTION 3: Composition/information on ingredients

3.2. Mixtures
   - Note that the table shows known hazards of the ingredients in pure form. These hazards are reduced or eliminated when mixed or diluted, see Section 16d.

<table>
<thead>
<tr>
<th>Constituent</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM AZIDE</td>
<td>Acute Tox 2oral, Aquatic Acute 1, Aquatic Chronic 1; $M = I$; H300, EUH032, H400, H410</td>
<td>&lt;0.01 %</td>
</tr>
<tr>
<td>CAS No: 26628-22-8</td>
<td>EC No: 247-852-1</td>
<td>Index No: 011-004-00-7</td>
</tr>
</tbody>
</table>

Explanation to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in normal font. Text in italics are specifications and/or complements used in the calculation of the classification of this mixture, see Section 16b.
SECTION 4: First aid measures

4.1. Description of first aid measures

Generally
In case of concern, or if symptoms occur, call a doctor/physician.

Upon breathing in
Fresh air and rest. If symptoms persist seek medical advice.

Upon eye contact
For safety reasons, flush eyes with water; If symptoms occur, seek medical advice.

Upon skin contact
Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

Upon ingestion
Rinse nose, mouth and throat with water.
Get medical attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed
No further relevant information available.

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

SECTION 5: Fire-fighting measures

5.1. Extinguishing media
Extinguish with water mist, powder, carbon dioxide or alcoholresistant foam.

5.2. Special hazards arising from the substance or mixture
In case of fire, substances hazardous to health, or substances harmful in other respects, may be dispersed.

5.3. Advice for fire-fighters
Protective measures should be taken regarding other material at the site of the fire.
In case of fire use a respirator mask.
Wear full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Avoid inhalation and exposure to skin and eyes.
Use recommended safety equipment, see section 8.
Ensure good ventilation.

6.2. Environmental precautions
Avoid emissions into soil, water or air.

6.3. Methods and material for containment and cleaning up
Absorb the liquid with an inert absorbent, vermiculite, for example. Collect the material for disposal at a waste disposal facility.

6.4. Reference to other sections
See section 8 and 13 for personal protection equipment and disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Avoid spillage, inhalation and contact with eyes and skin.
Do not eat, drink or smoke in premises where this product is handled.
Wash your hands after using the product.
Handle in premises which have modern ventilation standards.

7.2. Conditions for safe storage, including any incompatibilities
The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.
Store separately from food and animal fodder, incl. utensils or surfaces which have been in contact with these things.
Always use sealed and visibly labeled packages.
Store in a dry place at 2 - 8 °C.
The product is stable until the expiration date when stored under recommended conditions.

7.3. Specific end uses
See identified uses in Section 1.2.

SECTION 8: Exposure controls/personal protection
8.1. Control parameters
8.1.1. National limit values
SODIUM AZIDE

United Kingdoms (EH40/2005)
Time-weighted-average exposure limit (TWA) 0.1 mg/m³
Short term exposure limit (STEL) 0.3 mg/m³
Note Sk

Explanations of abbreviations are given in Section 16b

DNEL
No data available.
PNEC
No data available.

8.2. Exposure controls
No special measures need to be taken in the event of normal handling or use.

8.2.1. Appropriate engineering controls
Handle in premises which have modern ventilation standards.

Eye/face protection
Eye protection should be worn if there is any danger of direct exposure or splashing.

Skin protection
Use protective gloves fulfilling the standard EN374 if there is a risk of direct contact.

Respiratory protection
Protective breathing equipment should only be required in extreme work-situations. Consult the manufacturer if this is the case.

8.2.3. Environmental exposure controls
For limiting environmental exposure, see section 12.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance
   Form: solution. Colour: yellow.
b) Odour
   Not indicated
c) Odour threshold
   Not indicated
d) pH
   7.9
e) Melting point/freezing point
   Not indicated
f) Initial boiling point and boiling range
   Not indicated
g) Flash point
   Not indicated
h) Evaporation rate
   Not indicated
i) Flammability (solid, gas)
   Not applicable
j) Upper/lower flammability or explosive limits
   Not indicated
k) Vapour pressure
   Not indicated
l) Vapour density
   Not indicated
m) Relative density
   Not indicated
n) Solubility
   Not indicated
o) Partition coefficient: n-octanol/water
   Not applicable
p) Auto-ignition temperature
   Not indicated
q) Decomposition temperature
   Not indicated
r) Viscosity
   Not indicated
s) Explosive properties
   Not applicable
t) Oxidising properties
   Not applicable

9.2. Other information
No data available

SECTION 10: Stability and reactivity

10.1. Reactivity
The product contains no substances which can lead to hazardous reactions at normal use.

10.2. Chemical stability
The product is stable at normal storage and handling conditions.

10.3. Possibility of hazardous reactions
No hazardous reactions known during normal use.
10.4. Conditions to avoid
None in particular.

10.5. Incompatible materials
None known.

10.6. Hazardous decomposition products
None under normal conditions.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Not indicated.

Acute toxicity
The product is not classified as acute toxic.

SODIUM AZIDE
LD50 rabbit 24h: 50 mg/kg Dermally
LC50 rat 4h: 0.037 mg/L Inhalation
LD50 rat 24h: 27 mg/kg Orally

Skin corrosion/irritation
Can cause skin irritation after repeated or prolonged contact.

Serious eye damage/irritation
The product is not classified as irritant to the eyes.

Respiratory or skin sensitisation
Hypersensitive reactions cannot be ruled out for persons who are overtly sensitive.

Germ cell mutagenicity
No mutagenic effects have been reported for the substance in this mixture.

Carcinogenicity
No carcinogenic effects have been reported for the substances in this product.

Reproductive toxicity
No toxic effects to reproduction have been reported for the substances in this mixture.

STOT-single exposure
No known hazards for occasional exposure.

STOT-repeated exposure
No known hazards for repeated exposure.

Aspiration hazard
The product is not classified as being toxic for aspiration.

SECTION 12: Ecological information

12.1. Toxicity
Avoid larger spills in soil, water and drains.
No ecological damage is known or expected in the event of normal use.

12.2. Persistence and degradability
The product degrades in the natural environment.

12.3. Bioaccumulative potential
Neither this product, nor its contents, accumulates in nature.

12.4. Mobility in soil
The product is miscible with water and is therefore variable in soil and water.

12.5. Results of PBT and vPvB assessment
This product does not contain any substances that are assessed to be a PBT or a vPvB.

12.6. Other adverse effects
No known effects or hazards.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Waste handling of the product
Avoid discharge of undiluted product into sewers.
See also national waste regulations.
The product is not classified as hazardous waste.
Observe local regulations or contact the supplier for further information.

Classification according to 2006/12
Recommended LoW-code: 18 01 07 Chemicals other than those mentioned in 18 01 06
SECTION 14: Transport information

Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

14.1. UN number
Not classified as dangerous goods

14.2. UN proper shipping name
Not applicable

14.3. Transport hazard class(es)
Not applicable

14.4. Packing group
Not applicable

14.5. Environmental hazards
Not applicable

14.6. Special precautions for user
Not applicable

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Not applicable

14.8 Other transport information
Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Not indicated.

15.2. Chemical safety assessment
Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

SECTION 16: Other information

16a. Indication of where changes have been made to the previous version of the safety data sheet
Revisions of this document
This is the first version

16b. Legend to abbreviations and acronyms used in the safety data sheet
Full texts for Hazard Class and Category Code mentioned in section 3
Acute Tox 2oral Acute toxicity (Category 2 oral)
Aquatic Acute 1 Very toxic to aquatic life (Category Acute 1)
Aquatic Chronic 1; M = 1 Very toxic to aquatic life with long lasting effects to aquatic environments (Category Chronic 1)

Explanations of the abbreviations in Section 8
United Kingdom
Sk Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity

Explanations of the abbreviations in Section 14
ADR European Agreement concerning the International Transport of Dangerous Goods by Road
RID Regulations concerning the International Transport of Dangerous Goods by Rail
IMDG International Maritime Dangerous Goods Code
ICAO International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)
IATA The International Air Transport Association

16c. Key literature references and sources for data
Sources for data
Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex 1, as updated to 2018-03-12.
Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

Full texts for Regulations mentioned in this Safety Data Sheet


2006/12 DIRECTIVE 2006/12/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2006 on waste


16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

16e. List of relevant hazard statements and/or precautionary statements

Full texts for hazard statements mentioned in section 3

H300 Fatal if swallowed
EUH032 Contact with acids liberates very toxic gas
H400 Very toxic to aquatic life
H410 Very toxic to aquatic life with long lasting effects

16f. Advice on any training appropriate for workers to ensure protection of human health and the environment

Warning for misuse

This product is not expected to cause severe harm to humans or the environment. The manufacturer, the distributor or the supplier are not responsible for adverse effects if the product is not handled in accordance with the directions for use.

Other relevant information

Editorial information

This material safety data sheet has been prepared and checked by KemRisk®, KemRisk Sweden AB, Platensgatan 8, SE-582 20 Linköping, Sweden, www.kemrisk.se
SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
   Trade name: FXa Substrate
   Article number: 9080

1.2. Relevant identified uses of the substance or mixture and uses advised against
   Identified uses: Laboratory chemicals

1.3. Details of the supplier of the safety data sheet
   Company: Rossix AB
   Address: Taljegårdsgatan 3B, 43153 Mölndal, Sweden
   Telephone: +46 (0)31 7068965
   E-mail: info@rossix.com
   Website: www.rossix.com

1.4. Emergency telephone number
   Acute cases: Call 112, request poison information.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
   Upon assessment, this mixture is not classified as hazardous according to 1272/2008.

2.2. Label elements
   Hazard pictogram: Not applicable
   Signal word: Not applicable
   Hazard statement: Not applicable

2.3. Other hazards
   This product does not contain any substances that are assessed to be a PBT or a vPvB.
   Toxic p-nitroaniline is released during the assay, however the maximum concentration in the reaction mixture does not exceed 0.01%.

SECTION 3: Composition/information on ingredients

3.2. Mixtures
   Note that the table shows known hazards of the ingredients in pure form. These hazards are reduced or eliminated when mixed or diluted, see Section 16d.

<table>
<thead>
<tr>
<th>Constituent</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHYLENEDIAMINETETRAACETIC ACID DIPOTASSIUM MAGNESIUM SALT</td>
<td>Skin Irrit 2, Eye Irrit 2, STOT SE 3resp; H315, H319, H335</td>
<td>&lt;2 %</td>
</tr>
<tr>
<td>CAS No: 15708-48-2</td>
<td>EC No: 239-803-8</td>
<td></td>
</tr>
<tr>
<td>SODIUM AZIDE</td>
<td>Acute Tox 2oral, Aquatic Acute 1, Aquatic Chronic 1; M = 1; H300, EUH032, H400, H410</td>
<td>&lt;0.01 %</td>
</tr>
<tr>
<td>CAS No: 26628-22-8</td>
<td>EC No: 247-852-1</td>
<td></td>
</tr>
<tr>
<td>Index No: 011-004-00-7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Explanations to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in normal font. Text in italics are specifications and/or complements used in the calculation of the classification of this mixture, see Section 16b.

SECTION 4: First aid measures
4.1. Description of first aid measures

Generally

In case of concern, or if symptoms occur, call a doctor/physician.

Upon breathing in

Fresh air and rest. If symptoms persist seek medical advice.

Upon eye contact

For safety reasons, flush eyes with water; If symptoms occur, seek medical advice.

Upon skin contact

Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

Upon ingestion

Rinse nose, mouth and throat with water.

Get medical attention if you feel unwell.

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

No further relevant information available.

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

Symptomatic treatment.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Extinguish with water mist, powder, carbon dioxide or alcoholresistant foam.

5.2. Special hazards arising from the substance or mixture

In case of fire, substances hazardous to health, or substances harmful in other respects, may be dispersed.

5.3. Advice for fire-fighters

Protective measures should be taken regarding other material at the site of the fire.

In case of fire use a respirator mask.

Wear full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid inhalation and exposure to skin and eyes.

Use recommended safety equipment, see section 8.

Ensure good ventilation.

6.2. Environmental precautions

Avoid emissions into soil, water or air.

6.3. Methods and material for containment and cleaning up

Absorb the liquid with an inert absorbent, vermiculite, for example. Collect the material for disposal at a waste disposal facility.

6.4. Reference to other sections

See section 8 and 13 for personal protection equipment and disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid spillage, inhalation and contact with eyes and skin.

Do not eat, drink or smoke in premises where this product is handled.

Wash your hands after using the product.

Handle in premises which have modern ventilation standards.

7.2. Conditions for safe storage, including any incompatibilities

The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.

Store separately from food and animal fodder, incl. utensils or surfaces which have been in contact with these things.

Always use sealed and visibly labeled packages.

Store in a dry place at 2 - 8 °C.

The product is stable until the expiration date when stored under recommended conditions.

7.3. Specific end uses

See identified uses in Section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National limit values
DUST, INHALABLE

United Kingdoms (EH40/2005)
Time-weighted-average exposure limit (TWA) 10 mg/m³

DUST, RESPIRABLE

United Kingdoms (EH40/2005)
Time-weighted-average exposure limit (TWA) 4 mg/m³

SODIUM AZIDE

United Kingdoms (EH40/2005)
Time-weighted-average exposure limit (TWA) 0.1 mg/m³
Short term exposure limit (STEL) 0.3 mg/m³
Note Sk

Explanations of abbreviations are given in Section 16b

DNEL
No data available.
PNEC
No data available.

8.2. Exposure controls
No special measures need to be taken in the event of normal handling or use.

8.2.1. Appropriate engineering controls
Handle in premises which have modern ventilation standards.

Eye/face protection
Eye protection should be worn if there is any danger of direct exposure or splashing.

Skin protection
Use protective gloves fulfilling the standard EN374 if there is a risk of direct contact.

Respiratory protection
Protective breathing equipment should only be required in extreme work-situations. Consult the manufacturer if this is the case.

8.2.3. Environmental exposure controls
For limiting environmental exposure, see section 12.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
a) Appearance
   Form: solution. Colour: colourless to pale yellow.
b) Odour
   Not indicated
c) Odour threshold
   Not indicated
d) pH
   6.0
e) Melting point/freezing point
   Not indicated
f) Initial boiling point and boiling range
   Not indicated
g) Flash point
   Not indicated
h) Evaporation rate
   Not indicated
i) Flammability (solid, gas)
   Not applicable
j) Upper/lower flammability or explosive limits
   Not indicated
k) Vapour pressure
   Not indicated
l) Vapour density
   Not indicated
m) Relative density
   Not indicated
n) Solubility
   Not indicated
o) Partition coefficient: n-octanol/water
   Not applicable
p) Auto-ignition temperature
   Not indicated
q) Decomposition temperature
   Not indicated
r) Viscosity
   Not indicated
s) Explosive properties
   Not applicable
t) Oxidising properties
   Not applicable

9.2. Other information
No data available
SECTION 10: Stability and reactivity

10.1. Reactivity
The product contains no substances which can lead to hazardous reactions at normal use.

10.2. Chemical stability
The product is stable at normal storage and handling conditions.

10.3. Possibility of hazardous reactions
No hazardous reactions known during normal use.

10.4. Conditions to avoid
None in particular.

10.5. Incompatible materials
None known.

10.6. Hazardous decomposition products
None under normal conditions.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Not indicated.

Acute toxicity
The product is not classified as acute toxic.

SODIUM AZIDE
LD50 rabbit 24h: 50 mg/kg Dermally
LC50 rat 4h: 0.037 mg/L Inhalation
LD50 rat 24h: 27 mg/kg Orally

Skin corrosion/irritation
Can cause skin irritation after repeated or prolonged contact.

Serious eye damage/irritation
The product is not classified as irritant to the eyes.

Respiratory or skin sensitisation
Hypersensitive reactions cannot be ruled out for persons who are overtly sensitive.

Germ cell mutagenicity
No mutagenic effects have been reported for the substance in this mixture.

Carcinogenicity
No carcinogenic effects have been reported for the substances in this product.

Reproductive toxicity
No toxic effects to reproduction have been reported for the substances in this mixture.

STOT-single exposure
No known hazards for occasional exposure.

STOT-repeated exposure
No known hazards for repeated exposure.

Aspiration hazard
The product is not classified as being toxic for aspiration.

SECTION 12: Ecological information

12.1. Toxicity
Avoid larger spills in soil, water and drains.
No ecological damage is known or expected in the event of normal use.

12.2. Persistence and degradability
The product degrades in the natural environment.

12.3. Bioaccumulative potential
Neither this product, nor its contents, accumulates in nature.

12.4. Mobility in soil
The product is miscible with water and is therefore variable in soil and water.

12.5. Results of PBT and vPvB assessment
This product does not contain any substances that are assessed to be a PBT or a vPvB.

12.6. Other adverse effects
No known effects or hazards.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Waste handling of the product
Avoid discharge of undiluted product into sewers.  
The product is not classified as hazardous waste.  
Observe local regulations or contact the supplier for further information.  
See also national waste regulations.

**Classification according to 2006/12**  
Recommended LoW-code: 18 01 07 Chemicals other than those mentioned in 18 01 06

**SECTION 14: Transport information**  
Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway),  
ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

14.1. **UN number**  
Not classified as dangerous goods

14.2. **UN proper shipping name**  
Not applicable

14.3. **Transport hazard class(es)**  
Not applicable

14.4. **Packing group**  
Not applicable

14.5. **Environmental hazards**  
Not applicable

14.6. **Special precautions for user**  
Not applicable

14.7. **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**  
Not applicable

14.8 **Other transport information**  
Not applicable

**SECTION 15: Regulatory information**

15.1. **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
Not indicated.

15.2. **Chemical safety assessment**  
Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

**SECTION 16: Other information**

16a. **Indication of where changes have been made to the previous version of the safety data sheet**  
Revisions of this document

This is the first version

16b. **Legend to abbreviations and acronyms used in the safety data sheet**

**Full texts for Hazard Class and Category Code mentioned in section 3**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Irrit 2</td>
<td>Skin Irritant (Category 2)</td>
</tr>
<tr>
<td>Eye Irrit 2</td>
<td>Irritates eyes (Category 2)</td>
</tr>
<tr>
<td>STOT SE 3resp</td>
<td>Specific target organ toxicity - single exposure; May cause respiratory irritation (Category 3 resp)</td>
</tr>
<tr>
<td>Acute Tox 2oral</td>
<td>Acute toxicity (Category 2 oral)</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>Very toxic to aquatic life (Category Acute 1)</td>
</tr>
<tr>
<td>Aquatic Chronic 1; $M = 1$</td>
<td>Very toxic to aquatic life with long lasting effects to aquatic environments (Category Chronic 1)</td>
</tr>
</tbody>
</table>

**Explanations of the abbreviations in Section 8**

**United Kingdom**

Sk  Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity

**Explanations of the abbreviations in Section 14**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>European Agreement concerning the International Transport of Dangerous Goods by Road</td>
</tr>
<tr>
<td>RID</td>
<td>Regulations concerning the International Transport of Dangerous Goods by Rail</td>
</tr>
<tr>
<td>IMDG</td>
<td>International Maritime Dangerous Goods Code</td>
</tr>
<tr>
<td>ICAO</td>
<td>International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)</td>
</tr>
<tr>
<td>IATA</td>
<td>The International Air Transport Association</td>
</tr>
</tbody>
</table>
16c. Key literature references and sources for data

Sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2018-03-12. Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

Full texts for Regulations mentioned in this Safety Data Sheet


EH40/2005 EH40/2005 Workplace exposure limits

2006/12 DIRECTIVE 2006/12/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2006 on waste


16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

16e. List of relevant hazard statements and/or precautionary statements

Full texts for hazard statements mentioned in section 3

H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation
H300 Fatal if swallowed
EUH032 Contact with acids liberates very toxic gas
H400 Very toxic to aquatic life
H410 Very toxic to aquatic life with long lasting effects

16f. Advice on any training appropriate for workers to ensure protection of human health and the environment

Warning for misuse

This product is not expected to cause severe harm to humans or the environment. However the manufacturer, the distributor or the supplier cannot be responsible for unusual or criminal use of the product.

Other relevant information

Editorial information

This material safety data sheet has been prepared and checked by KemRisk®, KemRisk Sweden AB, Platensgatan 8, SE-582 20 Linköping, Sweden, www.kemrisk.se