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

1.1 Product identifier

Trofosfamid

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

1.2.1 Relevant uses

Cytostatic pharmaceutical

1.2.2 Uses advised against

None known.

1.3 Details of the supplier of the safety data sheet

Company

Baxter Oncology GmbH
Kantstraße 2
33790 Halle/Westfalen / GERMANY
Phone +49 (0) 5201 711 -0
Fax +49 (0) 5201 711-1735
Homepage www.baxter-oncology.com
E-mail info_de@baxter.com

Address enquiries to

Technical information info_de@baxter.com

Safety Data Sheet sdb@chemiebuero.de

1.4 Emergency telephone number

Advisory body +49 (0)89-19240 (24h) (english)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Carc. 1B: H350 May cause cancer.
Muta. 1A: H340 May cause genetic defects.
Repr. 1B: H360D May damage the unborn child.
Acute Tox. 3: H301 Toxic if swallowed.
STOT RE 1: H372 Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements

The product is required to be labelled in accordance with regulation (EC) No 1272/2008 (CLP).

Hazard pictograms

Signal word DANGER

Contains: Trofosfamide (C9 H18 Cl3 N2 O2 P)

Hazard statements

H350 May cause cancer.
H340 May cause genetic defects.
H360D May damage the unborn child.
H301 Toxic if swallowed.
H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P270 Do no eat, drink or smoke when using this product.
P280 Wear protective gloves / protective clothing / eye protection / face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER / doctor /…
P308+P313 IF exposed or concerned: Get medical advice / attention.
P330 Rinse mouth.
P405 Store locked up.
P501 Dispose of contents/container to in accordance with local/regional/national/international regulation.

Special labelling Restricted to professional users.

2.3 Other hazards

Human health dangers Carc. Cat. 1; Mut. Cat. 1; Repr. Cat. 1
Can be absorbed through the skin.

Other hazards Further hazards were not determined with the current level of knowledge.

SECTION 3: Composition / Information on ingredients

Product-type:

The product is a mixture.

Range [%]	Substance
100	Trofosfamide (C9 H18 Cl3 N2 O2 P)
	CAS: 22089-22-1, EINECS/ELINCS: 244-770-8
	GHS/CLP: Carc. 1B: H350 - Repr. 1B: H360D - Muta. 1A: H340 - Acute Tox. 3: H301 - STOT RE 1: H372

Comment on component parts Substances of Very High Concern - SVHC: substances are not contained or are below 0.1%.
For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information Adhere to personal protective measures when giving first aid.
Remove contaminated soaked clothing immediately and dispose of safely.

Inhalation Get medical advice.
Remove the victim into fresh air and keep him calm.

Skin contact Get medical advice.
In case of contact with skin wash off immediately with plenty of water.

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.

Ingestion Consult a doctor immediately.
Induce the patient to vomit of his own accord only if fully conscious.
Rinse out mouth and give plenty of water to drink.

4.2 Most important symptoms and effects, both acute and delayed

In case of therapeutical use of the substance, typical side effects are:
myelosuppression, gastro-intestinal complains, cystitis, hair loss, disorders of spermatogenesis or ovulation

4.3 Indication of any immediate medical attention and special treatment needed

Product is a cytotoxic agent.
After absorbing larger amounts of substance: Early endoscopy in order to assess mucosa lesions in the oesophagus and stomach which may appear. Suck away leftover substance.
Dialysis of the blood, monitoring of haemogram.

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media All extinguishing media are suitable but method must take into account the surrounding area to minimize dispersion.

Extinguishing media that must not be used Full water jet.

5.2 Special hazards arising from the substance or mixture

Risk of formation of toxic pyrolysis products.
Nitrogen oxides (NOx).
Hydrogen chloride (HCl).

5.3 Advice for firefighters

Use self-contained breathing apparatus.
Wear full protective suit.

Collect contaminated firefighting water separately, must not be discharged into the drains.
Fire residues and contaminated firefighting water must be disposed of in accordance within the local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Lock off contaminated area.
Use personal protective equipment.
Provide personnel decontamination immediately. Provide ready access to spill kit.
Use breathing apparatus if exposed to vapours/dust/aerosol.

6.2 Environmental precautions

Do not discharge into the soil/streches of water.

6.3 Methods and material for containment and cleaning up

Take up mechanically. Avoid production of dust.
Vacuum up spilled product with vacuum cleaner for carcinogenic substances.
Suitable container keep ready. Disposal in accordance to SECTION 13.
Clean contaminated areas afterwards thoroughly.

6.4 Reference to other sections

See SECTION 8+13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Encapsulation or vacuuming required.
Always close container tightly after removal of product. The product is to be handled only by regularly trained experts.
Provide suitable vacuuming at the processing machines.
Vent waste air to atmosphere only through suitable separators.

Take precautionary measures against static discharges.
Dust can form an explosive mixture with air.
Keep away from all sources of ignition - Refrain from smoking. Avoid production of dust.

Do not eat, drink or smoke when using this product.
Contaminated clothing should be changed and stored in a quarantined area until disposed of as hazardous waste.
Keep away from food and drink.

7.2 Conditions for safe storage, including any incompatibilities

Prevent penetration into the ground.
Ensure there are sufficient retaining facilities for water used to extinguish fire.
Keep only in unopened original container.

Do not store together with food.
Do not store together with oxidizing agents.
Do not store together with animal food/diet.

Keep under lock and key. Should only be accessible to specialists or people authorized by them.
Keep container in a well-ventilated place.
Keep in a cool place.
Store in a dry place.

7.3 Specific end use(s)

See product use, SECTION 1.2

SECTION 8: Exposure controls / personal protection

8.1 Control parameters

Ingredients with occupational exposure limits to be monitored (GB)

not applicable

8.2 Exposure controls

Additional advice on system design	Use appropriate fume hoods, e.g. safety work benches.
Eye protection	Tightly fitting goggles (EN 166:2001).
Hand protection	The details concerned are recommendations. Please contact the glove supplier for further information. In full contact: Latex, nitrile rubber (NBR), thickness min. 0,25 mm, within the finger crest range min. 0,5 mm; >60 min (EN 374-1/-2/-3). In splash contact: Latex, nitrile rubber (NBR), thickness min. 0,25 mm, within the finger crest range min. 0,5 mm; >60 min (EN 374-1/-2/-3).
Skin protection	Protective overalls.
Other	Personal protective equipment should be selected specifically for the working place, depending on concentration and quantity handled. The resistance of this equipment to chemicals should be ascertained with the respective supplier. Avoid contact with eyes and skin. Do not wear used work clothes outside of the work area. Mark work areas. If there is the possibility of skin/eye contact, the indicated hand/eye/body protection should be used.
Respiratory protection	If ventilation is insufficient, wear respiratory protection. Short term: filter apparatus, filter P3. (DIN EN 143)
Thermal hazards	No information available.
Delimitation and monitoring of the environmental exposition	When processing the product, the air in the workplace should be regularly monitored and employees exposed to the product should be given a regular medical check-up.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	crystalline
Color	white
Odor	odourless
Odour threshold	not determined
pH-value	not applicable
pH-value [1%]	not applicable
Boiling point [°C]	not determined
Flash point [°C]	not applicable
Flammability (solid, gas) [°C]	not determined
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Oxidising properties	no
Vapour pressure/gas pressure [kPa]	not applicable
Density [g/ml]	not determined
Bulk density [kg/m³]	not determined
Solubility in water	5 g/l (20°C)
Partition coefficient [n-octanol/water]	not determined
Viscosity	not applicable
Relative vapour density determined in air	not applicable
Evaporation speed	not determined
Melting point [°C]	49-53
Autoignition temperature [°C]	not applicable
Decomposition temperature [°C]	not determined

9.2 Other information

No information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

See SECTION 10.3.

10.2 Chemical stability

Stable under normal ambient conditions (ambient temperature).

10.3 Possibility of hazardous reactions

Reactions with acids, alkalies and oxidizing agents.
Decomposes on heating.

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

See SECTION 7

10.6 Hazardous decomposition products

Organic, nitrogenous products of decomposition and phosphoric compounds.
Halogenated hydrocarbons.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Substance
Trofosfamide (C9 H18 Cl3 N2 O2 P), CAS: 22089-22-1
LD50, oral, Rat: 202 mg/kg (Lit.).
NOEL, oral, Rat: 1,47 mg/kg (OECD 407, 182 d).
NOEL, oral, Rat: < 4,64 mg/kg (OECD 407, 28 d).

Serious eye damage/irritation	Based on the available information, the classification criteria are not fulfilled.
Skin corrosion/irritation	Based on the available information, the classification criteria are not fulfilled.
Respiratory or skin sensitisation	Based on the available information, the classification criteria are not fulfilled.
Specific target organ toxicity — single exposure	Based on the available information, the classification criteria are not fulfilled.
Specific target organ toxicity — repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Mutagenicity	Ames-Test, Salmonella typhimurium/E. coli, positive (literature). Micronucleus test, mouse, positive (literature).
Reproduction toxicity	On the basis of the findings in animal experiments, a probable risk of damage to the foetus must be assumed.
Carcinogenicity	Clues to possible carcinogenic effects in animal experiments.
Aspiration hazard	Based on the available information, the classification criteria are not fulfilled.
General remarks	In the case that product dust is inhalated following discomforts may appear: Irritation of mucous lining (nose, throat, eyes), cough, sneezing, flow of tears. In case of a therapeutical use of the product, typical side effects are: Myelosuppression, gastro-intestinal complains, cystitis, hair loss, disorders of spermatogenesis or ovulation. The toxiclogical data are those of the pure product. The toxicity data listed pertaining to the ingredients are intended for those working in the medicinal professions, experts for occupational health and safety and toxicologists.

SECTION 12: Ecological information

12.1 Toxicity

Substance
Trofosfamide (C9 H18 Cl3 N2 O2 P), CAS: 22089-22-1
LC50, (96h), Salmo gairdneri: > 1000 mg/l OECD203.
EC50, (48h), Daphnia magna: 162 mg/l OECD202.
NOEC, (48h), Daphnia magna: 100 mg/l OECD202.
NOEC, (96h), Salmo gairdneri: > 555 mg/l OECD203.

12.2 Persistence and degradability

Behaviour in environment compartments	not determined
Behaviour in sewage plant	not determined
Biological degradability	The organic component of the product is not easily biodegradable in accordance to OECD 301 E (<1% 28d).

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects

No ecotoxicological studies are available. Data from a comparable product: ifosfamide.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. It is not possible to determine a waste code for this product in accordance with the European Waste Catalogue (EWC) since it is only possible to classify it according to how it is used by the customer. The waste code is to be determined within the EU in liaison with the waste-disposal operator.

Product

Dispose of as hazardous waste.
Coordinate disposal with the disposal contractor/authorities if necessary.

Waste no. (recommended) 180108*

Contaminated packaging

Contaminated packing should be disposed of as product waste.
Coordinate disposal with the authorities if necessary.

Waste no. (recommended) 150110*

SECTION 14: Transport information

14.1 UN number

Transport by land according to ADR/RID	2811
Inland navigation (ADN)	2811
Marine transport in accordance with IMDG	2811
Air transport in accordance with IATA	2811

14.2 UN proper shipping name

Transport by land according to ADR/RID	Toxic solid, organic, n.o.s. (Trofosfamide)
- Classification Code	T2
- Label	
- ADR LQ	5 kg
- ADR 1.1.3.6 (8.6)	Transport category (tunnel restriction code) 2 (E)
Inland navigation (ADN)	Toxic solid, organic, n.o.s. (Trofosfamide)
- Classification Code	T2
- Label	
Marine transport in accordance with IMDG	Toxic solid, organic, n.o.s. (Trofosfamide)
- EMS	F-A, S-A
- Label	
- IMDG LQ	5 kg
Air transport in accordance with IATA	Toxic solid, organic, n.o.s. (Trofosfamide)
- Label	

14.3 Transport hazard class(es)

Transport by land according to ADR/RID	6.1
Inland navigation (ADN)	6.1
Marine transport in accordance with IMDG	6.1
Air transport in accordance with IATA	6.1

14.4 Packing group

Transport by land according to ADR/RID	III
Inland navigation (ADN)	III
Marine transport in accordance with IMDG	III
Air transport in accordance with IATA	III

14.5 Environmental hazards

Transport by land according to ADR/RID	no
Inland navigation (ADN)	no
Marine transport in accordance with IMDG	no
Air transport in accordance with IATA	no

14.6 Special precautions for user

Relevant information under SECTION 6 to 8.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

No information available.

SECTION 15: Regulatory information

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

EEC-REGULATIONS	1991/689 (2001/118); 2010/75; 2004/42; 648/2004; 1907/2006 (REACH); 1272/2008; 75/324/EEC (2008/47/EC); 453/2010/EC; (EU) 2015/830
TRANSPORT-REGULATIONS	DOT-Classification, ADR (2015); IMDG-Code (2015, 37. Amdt.); IATA-DGR (2016).
NATIONAL REGULATIONS (GB):	EH40/2005 Workplace exposure limits (Second edition, published December 2011). CHIP 3/ CHIP 4
- Observe employment restrictions for people	Observe employment restrictions for women of child-bearing age, for mothers-to-be and nursing mothers and for young people.
- VOC (2010/75/CE)	not applicable

15.2 Chemical safety assessment

A chemical safety assessment is not yet available for this substance.

SECTION 16: Other information

16.1 Hazard statements (SECTION 03)

H372 Causes damage to organs through prolonged or repeated exposure.
H301 Toxic if swallowed.
H340 May cause genetic defects.
H360D May damage the unborn child.
H350 May cause cancer.

16.2 Abbreviations and acronyms:

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route
RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses
ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure
CAS = Chemical Abstracts Service
CLP = Classification, Labelling and Packaging
DMEL = Derived Minimum Effect Level
DNEL = Derived No Effect Level
EC50 = Median effective concentration
ECB = European Chemicals Bureau
EEC = European Economic Community
EINECS = European Inventory of Existing Commercial Chemical Substances
ELINCS = European List of Notified Chemical Substances
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC-Code = International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IC50 = Inhibition concentration, 50%
IMDG = International Maritime Code for Dangerous Goods
IUCLID = International Uniform ChemicaL Information Database
LC50 = Lethal concentration, 50%
LD50 = Median lethal dose
MARPOL = International Convention for the Prevention of Marine Pollution from Ships
PBT = Persistent, Bioaccumulative and Toxic substance
PNEC = Predicted No-Effect Concentration
REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals
TLV®/TWA = Threshold limit value – time-weighted average
TLV®STEL = Threshold limit value – short-time exposure limit
VOC = Volatile Organic Compounds
vPvB = very Persistent and very Bioaccumulative

16.3 Other information

Customs Tariff not determined

Classification procedure
Carc. 1B: H350 May cause cancer. (Calculation method)
Muta. 1A: H340 May cause genetic defects. (Calculation method)
Repr. 1B: H360D May damage the unborn child. (Calculation method)
Acute Tox. 3: H301 Toxic if swallowed. (Calculation method)
STOT RE 1: H372 Causes damage to organs through prolonged or repeated exposure. (Calculation method)

Modified position SECTION 16 been added: GENERAL REVIEW [CLP; REACH-(EU) 2015/830]