

Safety Data Sheet

according to 1907/2006/EC, Article 31

Trade name: **Azelaic Acid**

Version: 6

Revision: 2022.05.06

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name	Azelaic Acid
CAS number	123-99-9

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

Recommended Use	SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites SU21 Consumer uses: Private households/general public/consumers SU22 Professional uses
Uses advised against	Not determined
Product category	PC39 Cosmetics, personal care products
Process category	PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions PROC 2: Use in closed, continuous process with occasional controlled exposure. PROC 3: Use in closed batch process (synthesis or formulation). PROC 5: Mixing or blending in batch processes PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities. PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities. PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing). PROC 14: Production of preparations or articles by tableting, compression, extrusion, pelletisation. PROC 15: Use as laboratory reagent
Environmental release category	ERC 2: Formulation into mixture
Application of the substance / the mixture	Cosmetic Skin cosmetics Cosmetic Active Agent Cosmetic auxiliary

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier
CORUM INC.
6FL., No.360, Ruei Guang Rd.,
Neihu Dist, Taipei 11492, Taiwan

Further information obtainable from
marketing.support@corum.com.tw

1.4 Emergency telephone number

Company phone number	CORUM Tel. 886-2-8751-6060 Fax. 886-2-8751-6363
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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

2.2 Label elements

Label according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

Hazard Pictograms



GHS07

Signal word

Warning

Hazard statements

H315 causes skin irritation

H319 causes serious eye irritation

Precautionary statements

P280

Wear protective gloves/protective clothing/eye protection/face protection.

P264

Wash thoroughly after handling.

P302+P352

If on skin: wash with plenty of water.

P305+P351+P338

If in eyes: rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P332+P313

If skin irritation occurs: Get medical advice/attention.

P337+P313

If eye irritation persists: Get medical advice/attention.

P362+P364

Take off contaminated clothing and wash it before reuse.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT:

The substance does not meet the PBT criteria (not PBT) according to (EC) 1907/2006, Annex XIII.

vPvB:

The substance does not meet the vPvB criteria (not vPvB) according to (EC) 1907/2006, Annex XIII.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Chemical characterization: Substances

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3.2 Composition/information on ingredients

Chemical Name	CAS No.	EC No.	Specific concentration limits
Nonanedioic acid (azelaic acid)	123-99-9	204-669-1	Skin Irrit. 2; H315: C ≥ 50 %

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information

Take affected persons out into the fresh air.
Do not leave affected persons unattended.
Seek medical treatment.

After inhalation

If breathing, move person into fresh air. If not breathing, give artificial respiration. Get medical attention.

After skin contact

Immediately rinse with water. Remove contaminated clothing, contaminated footwear and dispose of safely. Wash clothing before reuse. Get medical attention if symptoms occur.

After eye contact

Immediately flush eyes with copious amounts of water for at least 15 minutes. Check for and remove any contact lenses. Do not let the victim rub eyes. Dust and process vapors may cause eye irritation. Seek medical treatment.

After swallowing

Do not induce vomiting; call for medical help immediately. Rinse mouth with plenty of water. If a person is vomiting while laying on his back, place him in the recovery position (turned onto his side).

4.2 Most important symptoms and effects, both acute and delayed

Symptoms

Temporary skin irritation (pruritus, burning or and stinging)
Eye irritation

4.3 Indication of any immediate medical attention and special treatment needed

Note to physicians

Treatment should be in general symptomatic to relieve any effects.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use fire extinguishing methods suitable to surrounding conditions.

SMALL FIRE: Dry powder or carbon dioxide (CO₂) extinguisher, dry sand or fire fighting foam

LARGE FIRE: Use water spray, water fog or foam. DO NOT use direct water jet.

Unsuitable extinguishing media

Water with full jet

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Carbon oxides (CO_x)

Carbon monoxide (CO)

5.3 Advice for firefighters

Wear self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Additional Information

Combustible powder

Cool endangered receptacles with water spray

See section 9: information on powder explosibility

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothes.

Ensure adequate ventilation.

Avoid formation of dust.

Keep away from ignition sources.

Use respiratory protective device against the effects of fumes/dust/aerosol.

Keep unnecessary and unprotected personnel from entering.

Avoid contact with the spilled material. Do not touch or walk through spilled material.

Stop or contain leak at the source if safe to do so.

6.2 Environmental precautions

Do not allow to enter sewers/surface or ground water.

Inform respective authorities in case of seepage into water course or sewage system.

6.3 Methods and material for containment and cleaning up

Use non-sparking tools.

* Small spillage:

Pick up mechanically. Clean the area with water.

Dispose of the material collected according to regulations.

* Large spillage:

Large spills may be shoveled into containers.

Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the wastewater collection system. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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SECTION 7: HANDLING AND STORAGE
7.1 Precaution for safe handling**Advice on safe handling**

Prevent formation of dust.
 Ensure good ventilation/exhaustion at the workplace.
 Open and handle receptacle with care.
 Protect from heat.
 Keep ignition sources away - Do not smoke.
 Use explosion-proof apparatus / fittings and spark-proof tools.

7.2 Conditions for safe storage, including any incompatibilities**Storage conditions**

Protect from contacting with light, heat and moisture.
 Store in tightly closed container at 25°C in a dry place.

Incompatible materials

Store away from oxidizing agents.

Storage class (VbF)

No

7.3 Specific end use(s)

No further relevant information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION
8.1 Control parameters**Exposure limits**

Not required

DNEL

CAS: 123-99-9 azelaic acid		
Oral	DNEL systemic effects, long-term	2.5 mg/kg bw/day (population)
Dermal	DNEL systemic effects, long-term	5 mg/kg bw/day (population)
		10 mg/kg bw/day (workers)
Inhalative	DNEL systemic effects, long-term	4.348 mg/m ³ (population)
		17.632 mg/m ³ (workers)

PNEC

CAS: 123-99-9 azelaic acid	
PNEC water (freshwater)	0.02 mg/L (Freshwater invertebrates)
PNEC water (marine water)	0.002 mg/L (Marine water invertebrates)
PNEC sediment (marine water)	0.00931 mg/kg sed dw (marine water sediment organisms)
PNEC soil	0.00687 mg/kg soil dw (soil micro-organisms)
PNEC STP	912 mg/L (Micro-organisms)
PNEC water (int releases)	0.16 mg/L (Fish)

Additional information

The valid lists during this review were used as a basis.

8.2 Exposure controls

Appropriate engineering controls

Applying good personal hygiene practices, such as the proper handling of contaminated clothing, the use of washing facilities before entering public areas, and the restriction of eating, drinking, and smoking in designated areas are essential to prevent chemical contamination.

If user operations generate dust, fume or mist, use local exhaust ventilation or other engineering controls to keep exposure to airborne contaminants below the exposure limit. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Ventilation equipment should be explosion-resistant if explosive concentrations of material are present.

Personal protective equipment

Respiration protection

Use suitable respiratory protective device in case of insufficient ventilation. Recommended exposure limits have not been established for this material. Whether there is a need for respiratory protection under court conditions of handling of this material should be evaluated by a qualified health specialist.

Hands protection

Protective gloves



The glove material has to be impermeable and resistant to the product/the substance/the preparation. Due to missing tests no recommendation to the glove material can be given for the product/the preparation/the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection

Tightly sealed goggles



Wear safety glasses meeting the specifications of ansi standard Z87.1 where no contact with the eye is anticipated. Chemical safety goggles meeting the specifications of ansi standard Z87.1 should be worn whenever there is the possibility of splashing or other contact with the eyes.

General protective measure

Avoid contact with the eyes and skin.

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General hygiene measure	Do not inhale dust/smoke/mist. All skin and mucous membranes with potential exposure have to be protected with appropriate PPE.
Environmental exposure controls	No further relevant information available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
9.1 Information on basic physical and chemical properties

Physical State	Powder
Appearance	Powder
Color	White
Odor	Characteristic
Odor threshold	Not determined

Property

pH value (5%)	Not determined
Melting point/Melting range	105-109 °C (peer-reviewed literature)
Boiling point/Boiling range	357.1°C (peer-reviewed literature)
Flash point	180°C (Open cup)
Flammability (solid, gaseous)	Product is not flammable.
Ignition temperature	Not determined
Decomposition temperature	Not determined
Self-igniting	Not determined
Danger of explosion	Product does not present an explosion hazard.
Explosion limit	
Lower	50 g/m ³ (0.75 micron powder)
Upper	Not determined
Oxidizing properties	Not determined
Explosive properties	Not determined
Vapor pressure at 25°C	<1.33E-4 hPa (peer-reviewed database)
Vapor density	1.03 g/cm ³
Relative density at 25°C	1225 g/m ³ (peer-reviewed literature)
Evaporation rate	Not determined
Solubility	
water at 20 °C:	2.4 g/l (peer-reviewed literature)
alcohols at 20 °C:	N.D. g/l (SOLUBLE)
Partition coefficient (n-octanol/water at 20 °C)	1.57 log POW (peer-reviewed database)
Kinematic Viscosity	Not applicable
Dynamic Viscosity	Not applicable

9.2 Other information
Important information on protection of health and environment, and on safety

Explosive properties	The product is not explosive.
Softening point/range	Not applicable
Oxidising properties	According to the structure, this substance has no oxidizing properties.

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Information with regard to physical hazard classes

Explosives	Not applicable
Flammable gases	Not applicable
Aerosols	Not applicable
Oxidising gases	Not applicable
Gases under pressure	Not applicable
Flammable liquids	Not applicable
Flammable solids	Not applicable
Self-reactive substances and mixtures	Not applicable
Pyrophoric liquids	Not applicable
Pyrophoric solids	Not applicable
Self-heating substances and mixtures	Not applicable
Substances and mixtures, which emit flammable gases in contact with water	Not applicable
Oxidising liquids	Not applicable
Oxidising solids	Not applicable
Organic peroxides	Not applicable
Corrosive to metals	Not applicable
Desensitised explosives	Not applicable
Surface tension	Not applicable
Dissociation constant	pKa: 4.55 International Union of Pure and Applied chemistry London: Butterworth (1961), cited in HSDB
Granulometry	Not determined
Additional information	Azelaic acid powder explosibility data (test results for 0.75 micron powder) Minimum oxygen for combustion (MOC): 11.59 % Minimum Ignition Energy: 5-10 mJ Maximum explosion pressure (Pmax): 7.7 bar Maximum rate of pressure rise (DP/DT Max): 665 bar/sec

SECTION 10: STABILITY AND REACTIVITY
10.1 Reactivity

No hazardous reactions if stored and handled as prescribed/indicated.

10.2 Chemical stability

The product is stable under ordinary condition.

Thermal decomposition/conditions to be avoided

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

No hazardous reactions if stored and handled as prescribed/indicated.

10.4 Conditions to avoid

Avoid creating or accumulating fines or dusts.

Protect from contacting with light, heat and moisture.

10.5 Incompatible materials

Strong oxidizing agents.

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10.6 Hazardous decomposition products

No hazardous decomposition products if stored and handled as prescribed/indicated.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****Acute toxicity**

Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification

The values used for classification are taken by analogy to substances of similar structure.

CAS: 123-99-9 azelaic acid		
Oral	LD50	>10,000 mg/kg (rat) (OECD 401 with CAS 334-48-5)
	LD50	>2,000 mg/kg bw (rat) (OECD 401) with CAS 124-07-2)
Dermal	LD50 (static)	>2,000 ml/ kg bw (rabbit) (OECD 434) with CAS 57-11-4)
Inhalative	LC50/4 h	>0.152 mg/L/air (rat) (flowing stream of saturated vap. with CAS 124-07-2)

Primary Irritant effect**Skin corrosion/irritation**

Irritant to skin

Skin irritation has been reported in exposure to animals and workers handling azelaic acid (peer reviewed database).

Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. ohn Wiley & Sons. New York, N.Y. (2001)., p. 5:772]

Classification by analogy to substances of similar structure.

CAS number: 68937-75-7

Method: equivalent or similar to OECD Test Guideline 404 (Acute skin irritation/corrosion)

Species: Rabbit

Serious eye damage/irritation

Adverse effects observed (irritating).

Eye irritation has been reported in exposure to animals and workers handling azelaic acid (peer reviewed database).

Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. ohn Wiley & Sons. New York, N.Y. (2001)., p. 5:772]

Classification by analogy to substances of similar structure.

CAS number: 334-48-5

Equivalent or similar to OECD 405 (Acute Eye

Irritation/Corrosion) in rabbits, New Zealand White (male)

Respiratory/skin sensitization

Based on available data, the classification criteria are not met.

Method study: equivalent or similar to OECD Guideline 406 (Skin Sensitisation)

Additional toxicological information**Toxicokinetics, metabolism and distribution**

Azelaic acid is excreted through urine (mean of 76.9% of infused dose). Reported in HDSB, Bertuzzi A et al; Clin Pharmacokinet 20 (5):411-9 (1991)

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Repeated dose toxicity Based on available data, the classification criteria are not met.
Read across from structural analogue CAS 112-85-6.

CAS: 123-99-9 azelaic acid		
Oral	NOAEL Rep. Dose	1,000 mg/kg bw/d (rat) (OECD 422) with CAS 112-85-6

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Germ Cell mutagenicity Based on available data, the classification criteria are not met.
Read-across from available studies with analogue substances (fatty acids, category approach)
Negative findings in bacterial reverse mutation test (Ames test OECD 471), chromosome aberration test (OECD 473) and gene mutation test in mammalian cells (OECD 476)

Carcinogenicity No further relevant information available.

Reproductive toxicity Based on available data, the classification criteria are not met.

CAS: 123-99-9 azelaic acid		
Oral	NOAEL (repr)	1,000 mg/kg bw/day (rat) (OECD 422) with CAS 112-85-6

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

11.2 Information on toxicological effects

Endocrine disrupting properties Substance is not listed.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity Based on available data, the classification criteria are not met.

CAS: 123-99-9 azelaic acid	
EC10 (static)	912 mg/L (Pseudomonas putida) (equivalent or similar to ISO 10712 with CAS 124-07)
LC50/96 h (static)	>16 mg/L /meas. (geom (Oryzias latipes) (OECD 203) with CAS 334-48-5)
EC50/48h	>20 mg/L /based on mo (Daphnia sp.) (OECD 202) with CAS 334-48-5)
EC50/72h	>67 mg/L /meas. TWA (Pseudokirchneriella subcapitata) (2) with CAS 123-99-9)
NOEC (28d) (dynamic)	2 mg/L /based on mort (Danio rerio) (OECD 305E) with CAS 629-25-4)
NOEC/21d (static)	0.2 mg/L /semi-static (Daphnia sp.) (OECD 211) with CAS 334-48-5)

12.2 Persistence and degradability

Readily biodegradable

Based on ready biodegradability studies with structural analogues (category approach: fatty acids).
Degree of degradability: 105 % in 30 days (closed bottle test, OECD 301D).

The substance does not contain chromophores that absorb at wavelengths > 290 nm and therefore is not expected to be susceptible to direct photolysis by sunlight.

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12.3 Bioaccumulative potential

Literature data of a similar substance

BCF: 3,162 L/kg ww or dimensionless

The estimated BCF of 3 suggests the potential for bioconcentration in aquatic organisms is low.

12.4 Mobility in soil

log Koc: 1.02 (prediction KOCWIN v. 2.00, MCI-method)

If released to soil, the substance is expected to have moderate mobility based upon an estimated Koc of 10.57.

The pKa of the substance is 4.55, indicating that this compound will exist almost entirely in the anion form in the environment and anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts.

Additional ecological information

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

PBT:

The substance does not meet the PBT criteria (not PBT) according to (EC) 1907/2006, Annex XIII.

vPvB:

The substance does not meet the vPvB criteria (not vPvB) according to (EC) 1907/2006, Annex XIII.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

No further relevant information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation

Smaller quantities can be disposed of with household waste.
Observe all federal, state and local environmental regulations

13.2 Uncleaning packaging

Recommendation

Disposal must be made according to official regulations.

Recommended cleansing agents

Water, if necessary together with cleansing agents.

SECTION 14: TRANSPORT INFORMATION

14.1 UN-Number

ADR/RID

Not applicable

ADN

Not applicable

IMDG

Not applicable

IATA

Not applicable

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14.2 UN proper shipping name

ADR/RID	Not applicable
ADN	Not applicable
IMDG	Not applicable
IATA	Not applicable

14.3 Transport hazard class(es)

ADR/RID	Not applicable
ADN	Not applicable
IMDG	Not applicable
IATA	Not applicable

14.4 Packing group

ADR/RID	Not applicable
ADN	Not applicable
IMDG	Not applicable
IATA	Not applicable

14.5 Environmental hazard

Marine pollutant	No
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14.6 Special precautions for user

Special precaution for user	Not applicable
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14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

14.8 ICAO/IATA – DGR

Not regulated as dangerous good

SECTION 15: REGULATORY INFORMATION**15.1 Safe, health and environmental regulations/legislation specific for the substance or mixture****Inventory - United States - Toxic Substances Control Act (TSCA)**

Substance is listed.

Inventory - Canada - Domestic Substances List (DSL)

Substance is listed.

Inventory - Canada – Non-Domestic Substances List (NDSL)

Substance is not listed.

European Inventory of Existing Chemical Substances (EINECS)

Substance is listed.

Japan Existing and New Chemical Substances (ENCS)

Substance is listed.

China Inventory of Existing Chemical Substance (IECSC)

Substance is listed.

Korean Existing and Evaluated Chemical Substances (KECL)

Substance is listed.

Philippines Inventory of Chemicals and Chemical Substances (PICCS)

Substance is listed.

Australian Inventory of Chemical Substances (AICS)

Substance is listed.

New Zealand Inventory of Chemicals

Substance is listed.

TCSI - Taiwan Chemical Substance Inventory

Substance is listed.

OECD – List of High Production Volume Chemicals

Substance is not listed.

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

Substance is not listed.

REGULATION (EU) 2019/1148**Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

Substance is not listed.

Annex II – REPORTABLE EXPLOSIVES PRECURSORS

Substance is not listed.

National regulations**Other regulations, limitations and prohibitive regulations**

Not determined

Substances of very high concern (SVHC) according to REACH, Article 59(10)

Substance is not listed.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

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Abbreviations and acronymsNOAEL: Non Observed Adverse Effect Level

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LOAEL: Lowest Observed Adverse Effect Level
NOEC: No Observed Effect Concentration
GHS: Globally Harmonized System of Classification and Labeling Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstract Service (division of the American Chemical Society)
VbF: Ordinance on the storage of combustible liquids, Austria
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
SVHC: Substances of Very High Concern
PBT: Persistent Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
STOT: Specific Target Organ Toxicity
ADR: Agreement on Dangerous Goods by Road
RID: Regulations concerning the Intl Transport of Dangerous Goods by Rail
ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IMDG: International Maritime Dangerous Goods
IATA: International Air Transport Association
BCF: Bioconcentration Factor
ChV: Fish Chronic Toxicity Value

Sources

Own data from manufacture
Hazardous Substances Data Bank (HSDB), a database of the National Library of Medicine's TOXNET system (<http://toxnet.nlm.nih.gov>)
REACH Registration data.