

Safety Data Sheet

according to 1907/2006/EC, Article 31, (Commission Regulation (EU) 2020/878)

Trade name: **Azelaic Acid**

Version: 7

Revision: 2024.03.27

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 114729, 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**

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.

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:**

Based on available data, the ingredients of this mixture do not meet the PBT criteria (not PBT) according to (EC) 1907/2006, Annex XIII.

vPvB:

Based on available data, the ingredients of this mixture do not meet the vPvB criteria (not vPvB) according to (EC) 1907/2006, Annex XIII.

Determination of endocrine-disrupting properties

The product does not contain ingredients with endocrine-disrupting properties for humans.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Composition/information on ingredients

Name	Chemical name	Identification	Classification	SCLs, M-Factors	%
COMPONENT					
Azelaic Acid	Nonanedioic acid	(CAS No.) 123-99-9 (EC No.)	Skin Irrit. 2 H315 Eye Irrit. 2 H319	Skin Irrit. 2; H315: C ≥ 50 %	100%

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3.2 Mixtures

Not applicable

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)

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Carbon monoxide (CO)

5.3 Advice for firefighters

Protective equipment:

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.

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.

Information about fire - and explosion protection:

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No special measures required.

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
Requirements to be met by storerooms and receptacles	No special measures required.
Information about storage in common storage facility	Not required
Further information about storage conditions	None

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace

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.

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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.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures

Avoid contact with the eyes and skin. Wash hands before breaks and at the end of work.

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.

General hygiene measure

Do not inhale dust/smoke/mist.

Environmental exposure

All skin and mucous membranes with potential exposure have to be protected with appropriate PPE.

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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
<u>Property</u>	
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	1.225 g/cm 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.

Information with regard to physical hazard classes

Explosives	Void
Flammable Gases and Chemically Unstable Gases	Void
Flammable Aerosols	Void
Oxidising Gases	Void

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Gases Under Pressure	Void
Flammable Liquids	Void
Flammable Solids	Void
Self-reactive Substances and Mixtures	Void
Pyrophoric Liquids	Void
Pyrophoric Solids	Void
Self-heating Substances and Mixtures	Void
Substances and Mixtures which in contact with water emit flammable gases	Void
Oxidising Liquids	Void
Oxidising Solids	Void
Organic Peroxides	Void
Substances and Mixtures corrosive to Metals	Void
Desensitized Explosives	Void
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.

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

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Name	Azelaic Acid CAS:123-99-9
Acute toxicity	*According to DSD (67/548/EEC) or CLP (1272/2008/EC) classification criteria for acute toxicity, azelaic acid does not fulfill the criteria for classification and thus a non-classification is warranted for this endpoint. *Oral, LD50 >10,000 mg/kg bw (rat)
Skin corrosion/irritation	*Adverse effect observed (irritating). 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] Cutaneous compatibility is very good. (dilution at 10% and 20%)
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]
Respiratory/skin sensitization	*No adverse effect observed (not sensitising). According to DSD (67/548/EEC) or CLP (1272/2008/EC) classification criteria for skin sensitisation, fatty acids do not fulfill the criteria for classification and thus a non-classification is warranted for this endpoint.
Respiratory tract	Not determined
Toxicokinetics, metabolism and distribution	*Azelaic acid is excreted through urine (mean of 76.9% of and distribution infused dose). Reported in HDSB, Bertuzzi A et al; Clin Pharmacokinet 20 (5):411-9 (1991)
Repeated dose toxicity	*Reliable studies on oral repeated dose toxicity are available for the following category members: Subchronic: NOAEL oral = ca. 5000 mg/kg bw/d; CAS# 143-07-7, C12 (Fitzhugh 1960) Subchronic: NOAEL oral = 1000 mg/kg bw/d; CAS# 112-85-6, C22 (Nagao 2002) According to DSD (67/548/EEC) or CLP (1272/2008/EC) classification criteria for repeated dose toxicity, fatty acids do not fulfill the criteria for classification and thus a non-classification is warranted for this endpoint.
Germ Cell mutagenicity	*No adverse effect observed (negative). According to DSD (67/548/EEC) or CLP (1272/2008/EC) classification criteria for genetic toxicity, fatty acids do not fulfill the criteria for classification and thus a non-classification is warranted for this endpoint. *Azelaic acid was not mutagenic in an Ames Salmonella test, Chinese hamster ovary HGPRT mutation assay, and a dominant lethal test (species not specified). Reported in HDSB [Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. 5:772]
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	*Oral NOAEL (repr) 1,000 mg/kg bw/day, rat (with CAS 112-85-6). According to DSD (67/548/EEC) or CLP (1272/2008/EC) classification criteria for toxicity to reproduction/developmental toxicity/teratogenicity, fatty acids do not fulfill the criteria for classification and thus a non-classification is warranted for this endpoint.
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.

*from ECHA webpage registration data

11.2 Information on toxicological effects

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Endocrine disrupting properties

Substance is not listed.

SECTION 12: ECOLOGICAL INFORMATION

Name	Azelaic Acid CAS:123-99-9
12.1 Toxicity Aquatic toxicity	<p>*EC10 (static): 912 mg/L (Pseudomonas putida) (equivalent or similar to ISO 10712 with CAS 124-07)</p> <p>*LC50/96 h (static): >16 mg/L /meas. (geom (Oryzias latipes) ({OECD 203} with CAS 334-48-5)</p> <p>*EC50/48h: >20 mg/L /based on mo (Daphnia sp.) ({OECD 202} with CAS 334-48-5)</p> <p>*EC50/72h: >67 mg/L /meas. TWA (Pseudokirchneriella subcapitata) ({2} with CAS 123-99-9)</p> <p>*NOEC (28d) (dynamic): 2 mg/L /based on mort (Danio rerio) ({OECD 305E} with CAS 629-25-4)</p> <p>*NOEC/21d (static): 0.2 mg/L /semi-static (Daphnia sp.) ({OECD 211} with CAS 334-48-5)</p> <p>Based on available data, the classification criteria are not met.</p>
12.2 Persistence and degradability	<p>*Readily biodegradable.</p> <p>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.</p>
12.3 Bioaccumulative potential	<p>*Literature data of a similar substance</p> <p>BCF: 3,162 L/kg ww or dimensionless</p> <p>The estimated BCF of 3 suggests the potential for bioconcentration in aquatic organisms is low.</p>
12.4 Mobility in soil	<p>*log Koc: 1.02 (prediction KOCWIN v. 2.00, MCI-method)</p> <p>If released to soil, the substance is expected to have moderate mobility based upon an estimated Koc of 10.57.</p> <p>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.</p>
12.5 Results of PBT and vPvB assessment	<p>PBT: Not applicable</p> <p>vPvB: Not applicable</p>
12.6 Endocrine disrupting properties	The product does not contain substances with endocrine disrupting properties.
12.7 Other adverse effects	<p>Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water</p> <p>Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.</p>

*from ECHA webpage registration data

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.

European waste catalogue
HP4

Irritant - skin irritation and eye damage

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Substances Control Act (TSCA)	
Inventory - Canada - Domestic Substances List (DSL)	Y
Inventory - Canada - Non-Domestic Substances List (NDSL)	N
Inventory - Canada - Revised In Commerce List (R-ICL)	N
ECHA Inventory of substances	Y
Japan Existing and New Chemical Substances (ENCS)	Y
Inventory of Existing Chemical Substances in China (IECSC)	Y
Korean Existing and Evaluated Chemical Substances (KECL)	Y
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	Y
Australian Inventory of Industrial Chemicals (AIIC)	Y
New Zealand Inventory of Chemicals	Y
TCSI - Taiwan Chemical Substance Inventory	Y
OECD - List of High Production Volume Chemicals	N

Y : listed, N : not listed, E : exempted

Directive 2004/42/EC

Seveso category

Substance is 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.

Regulation (EC) No 273/2004 on drug precursors

Substance is not listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

Substance is not listed.

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer - ANNEX I (Ozone-depleting potential)

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.

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15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

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Abbreviations and acronyms

NOAEL: Non Observed Adverse Effect Level
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