Safety Data Sheet according to 1907/2006/EC, Article 31

Version: 6

Trade name: Azelaic Acid

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 subs	tance 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 tabletting,			
		compression, extrusion, pelletisation.			
		PROC 15: Use as laboratory reagent			
	Environmental release category	ERC 2: Formulation into mixture			
	Application of the substance / the m	ixture			
		Cosmetic			
		Skin cosmetics			
		Cosmetic Active Agent			
		Cosmetic auxiliary			
.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				
.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

Classification of the substance or mixture 2.1 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



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. If in eyes: rinse cautiously with water for serval minutes. Remove contact lenses, if present and easy to do. Continue P305+P351+P338 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 effe	cts both acute and delayed
	Symptoms	Temporary skin irritation (pruritus, burning or and stinging) Eye irritation
4.3	Indication of any immediate medica	I 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.

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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

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<u>Advice for firefighters</u> 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.

<u>Methods and material for containment and cleaning up</u> Use non-sparking tools. 6.3

* Small spillage: 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. <u>Reference to other sections</u> See Section 7 for information on safe handing. 6.4

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 t Open and handle receptacle with care. Protect from heat. Keep ignition sources away - Do not sr Use explosion-proof apparatus / fittings	noke.			
7.2	Conditions for safe storage, incl	uding any incompatibilities				
	Storage conditions	Protect from contacting with light, heat Store in tightly closed container at 25°C				
	Incompatible materials	Store away from oxidizing agents.				
	Storage class (VbF)	No				

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 <u>Control parameters</u>

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

FNEC			
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 organ 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.			

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.2	Exposure controls		
	Appropriate engineering controls	handling of contaminated clo before entering public areas, drinking, and smoking in des prevent chemical contaminal If user operations generate of exhaust ventilation or other e exposure to airborne contam Ensure that dust-handling sy dust collectors, vessels, and	tust, fume or mist, use local engineering controls to keep inants below the exposure limit. 'stems (such as exhaust ducts, processing equipment) are vent the escape of dust into the akage from the equipment). I be explosion-resistant if
	Personal protective equipment		
	Respiration protection	not been established for this need for respiratory protecti	tective device in case of ommended exposure limits have is material. Whether there is a ion under court conditions of ould be evaluated by a qualified
	Hands protection	Protective gloves	
		product/the substance/the p no recommendation to the o product/the preparation/the	e impermeable and resistant to th oreparation. Due to missing tests glove material can be given for th chemical mixture. Selection of eration of the penetration times, egradation
	Material of gloves		e gloves does not only depend or ther marks of quality and varies facturer.
	Penetration time of glove material		ne has to be found out by the ive gloves and has to be bserved
	Eye protection		ontact with the eye is anticipated. eeting the specifications of ansi /orn whenever there is the
	General protective measure	Avoid contact with the eyes	and skin.

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	General hygiene measure	Do not inhale dust/smoke/n All skin and mucous mem to be protected with appro	oranes with potential exposure have	
	Environmental exposure controls	No further relevant information	ation available	
	SECTION 9: PHYS	SICAL AND CHEMICAL P	ROPERTIES	已註解[CM1]:比對後替換為更新 SDS 的數
9.1	Information on basic physical and	d chemical properties		
•	Physical State	Powder		
	Appearance	Powder		
	Color	White		
	Odor	Characteristic		
	Oder threshold	Not determined		
	<u>Property</u>			
	pH value (5%)	Not determined		
	Melting point/Melting range Boiling point/Boiling range	105-109 °C (peer-reviewed 357.1°C (peer-reviewed lite		
	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 Explosion limit	Product does not present a		
	Lower Upper	50 g/m ³ (0.75 micron powde Not determined	er)	
	Oxidizing properties	Not determined		
	Explosive properties	Not determined		
	Vapor pressure at 25°C	<1.33E-4 hPa (peer-review)	ed database)	
	Vapor density	1.03 g/cm ³		
	Relative density at 25°C	1225 g/m3 (peer-reviewed l	literature)	
	Evaporation rate	Not determined		
	Solubility			
	water at 20 °C:	2.4 g/l (peer-reviewed litera	ture)	
	alcohols at 20 °C:	N.D. g/I (SOLUBLE)	-,	
	Partition coefficient			
	(n-octanol/water at 20 °C)	1.57 log POW (peer-review	ed database)	
	Kinematic Viscosity	Not applicable		
	Dynamic Viscosity	Not applicable		
9.2	Other information Important information on protect	ion of health and environment	t, and on safety	
	Explosive properties	The product is not explosiv		
	Softening point/range	Not applicable		
	Oxidising properties	According to the structure,	this substance has no	
		oxidizing properties.		

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Revision: 2022.05.06 Trade name: Azelaic Acid Version: 6 Information with regard to physical hazard classes Explosives Flammable gases Not applicable Not applicable Not applicable Aerosols Oxidising gases Not applicable Not applicable Gases under pressure Not applicable Flammable liquids Not applicable Flammable solids Self-reactive substances and mixtures Not applicable Not applicable **Pyrophoric liquids** 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 Not determined Granulometry 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 <u>Hazardous decomposition products</u> No hazardous decomposition products if stored and handled as prescribed/indicated.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity Based LD/LC50 values relevant for classification Based on available data, the classification criteria are not met.

The values used for classification are taken by analogy to substances of similar structure. CAS: 123-99-9 azelaic acid

Oral	LD50 LD50	>10,000 mg/kg (rat) (OECD 401 with CAS 334-48-5) >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 & amp; 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 & amp; 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 informati	on

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.	
CAS: 123-99-9 azelaic acid	Read across from structural ana	logue CAS 112-85-6.
Oral NOAEL Rep. Dose	1,000 mg/kg bw/d (rat) ({OECD 4	422} with CAS 112-85-6)
CMR effects (carcinogenity, mutage		
Germ Cell mutagenicity	Based on available data, the cla met. Read-across from available stud (fatty acids, category approach Negative findings in bacterial rev OECD 471), chromosome aberr test (OECD 473) and gene muta (OECD 476)	ssification criteria are not lies with analogue substances n) verse mutation test (Ames test ation
Carcinogenicity	No further relevant information a	vailable.
Reproductive toxicity	Based on available data, the clas	ssification criteria are not met.
CAS: 123-99-9 azelaic acid		
Oral NOAEL (repr)	1,000 mg/kg bw/day (rat) ({OEC	D 422} with CAS 112-85-6)
STOT-single exposure	Based on available data, the clas	ssification criteria are not met.
STOT-repeated exposure	Based on available data, the clas	ssification criteria are not met.
Aspiration hazard	Based on available data, the clas	ssification 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 <u>Persistence and degradability</u> Readily biodegradable Based on ready bidodegradability studies with strucutral 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 Recommended cleansing agents

Disposal must be made according to official regulations. Water, if necessary together with cleansing agents.

SECTION 14: TRANSPORT INFORMATION

Not applicable Not applicable Not applicable Not applicable

14.1 UN-Number

ADR/RID ADN	
IMDG	
IATA	

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14.2 UN pro	per shipping name		
ADR/R	ID	Not applicable	
ADN		Not applicable	
IMDG		Not applicable	
IATA		Not applicable	
14.3 Transp	ort hazard class(es)		
ADR/R	ID	Not applicable	
ADN		Not applicable	
IMDG		Not applicable	
IATA		Not applicable	
14.4 Packin	g group		
ADR/R	ID	Not applicable	
ADN		Not applicable	
IMDG		Not applicable	
IATA		Not applicable	
14.5 <u>Enviro</u>	nmental hazard		
Marine	pollutant	No	
14.6 Specia	I precautions for user		
	I precaution for user	Not applicable	
		nnex II of MARPOL73/78 and the	e IBC Code
Not app	blicable		
	ATA – DGR		
Not reg	ulated 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.

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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 acronyms

NOAEL: 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 International Carriage of Dangerous Goods by Inland Waterways IMDG: International Airtime Dangerous Goods IATA: International Airtime 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.