

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

Trade name: **Azelaic Acid**

Version: 7

Revision: 2023.10.02

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

1.1	<u>Product identifier</u> Trade name	Azelaic Acid			
	CAS number	123-99-9			
1.2	2 <u>Relevant identified uses of the substance or mixture and uses advised against</u>				
	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 8a: Transfer of substance or p		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 Application of the substance / the r	ERC 2: Formulation into 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 <u>Emergency telephone number</u> Company phone number

CORUM Tel. 886-2-8751-6060 Fax. 886-2-8751-6363



2.1

Safety Data Sheet

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SECTION 2: HAZARDS IDENTIFICATION Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008Skin Irrit. 2H315 Causes skin irritation.Eye Irrit. 2H319 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 serval 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 <u>Substances</u>

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 <u>Mixtures</u>

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 effect	cts, both acute and delayed
	Symptoms	Temporary skin irritation (pruritus, burning or and stinging) Eye irritation
4.3	Indication of any immediate medica	l 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 <u>Advice for firefighters</u>

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 <u>Personal precautions, protective equipment and emergency procedures</u>

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 <u>Environmental precautions</u>

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 <u>Reference to other sections</u>

See Section 7 for information on safe handing. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

7.1 <u>Precaution for safe handling</u> 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, includ	ing 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 storero	oms and receptacles		
		No special measures required.		
	Information about storage in common storage facility			
Not required		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	
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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/m³ (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

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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	exposure to airborne contain Ensure that dust-handling sy dust collectors, vessels, and designed in a manner to pre work area (i.e., there is no le Ventilation equipment should explosive concentrations of	engineering controls to keep ninants below the exposure limit. ystems (such as exhaust ducts, l processing equipment) are event the escape of dust into the eakage from the equipment). d be explosion-resistant if material are present.
Individual protection measures, such General protective and hygienic mea		upment
General protective and hygienic mea		and skin. Wash hands before
	breaks and at the end of wo	
Personal protective equipment	Lleo suitable respiratory pro	atactiva davica in casa of
Respiration protection	not been established for thi need for respiratory protect	otective device in case of ommended exposure limits have is material. Whether there is a tion under court conditions of ould be evaluated by a qualified
Hands protection	Protective gloves	
	The glove material has to b product/the substance/the no recommendation to the product/the preparation/the	e impermeable and resistant to the preparation. Due to missing tests glove material can be given for the e chemical mixture. Selection of deration of the penetration times, egradation
Material of gloves		e gloves does not only depend on rther marks of quality and varies ıfacturer.
Penetration time of glove material	•	ne has to be found out by the tive gloves and has to be bserved.
Eye protection	standard Z87.1 where no c	
General protective measure	Avoid contact with the eyes	
General hygiene measure	Do not inhale dust/smoke/mi All skin and mucous memb to be protected with approp	ranes with potential exposure have
Environmental exposure		······································



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controls

No further relevant information available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Powder Powder White

Characteristic Not determined

9.1 Information on basic physical and chemical properties

Physical State	
Appearance	
Color	
Odor	
Oder threshold	

Property

pH value (5%) Melting point/Melting range Boiling point/Boiling range Flash point Flammability (solid, gaseous) Ignition temperature **Decomposition temperature** Self-igniting Danger of explosion **Explosion limit** Lower Upper **Oxidizing properties Explosive properties** Vapor pressure at 25°C

Vapor density

Relative density at 25°C

Evaporation rate Solubility water at 20 °C: alcohols at 20 °C: Partition coefficient (n-octanol/water at 20 °C) **Kinematic Viscosity** Dynamic Viscosity

Not determined 105-109 °C (peer-reviewed literature) 357.1°C (peer-reviewed literature) 180°C (Open cup) Product is not flammable. Not determined Not determined Not determined Product does not present an explosion hazard. 50 g/m³ (0.75 micron powder) Not determined Not determined Not determined <1.33E-4 hPa (peer-reviewed database) 1.03 g/cm3 1225 g/m3 (peer-reviewed literature)

Not determined

2.4 g/l (peer-reviewed literature) N.D. g/I (SOLUBLE)

1.57 log POW (peer-reviewed database) Not applicable Not applicable

9.2 Other information

> **Explosive properties** Softening point/range **Oxidising properties**

Important information on protection of health and environment, and on safety The product is not explosive. Not applicable 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 Mixt	ures	
	Void	
Pyrophoric Liquids	Void	
Pyrophoric Solids	Void	
Self-heating Substances and Mixtu	ires	
-	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	e to Metals	
	Void	
Desensitized Explosives	Void	
Surface tension	Not applicable	
Dissociation constant	pKa: 4.55 International Union of Pure and	
	London: Butterworth (1961), cited in HSD	В
Granulometry	Not determined	
Additional information	Azelaic acid powder explosibility data (tes micron powder)	t results for 0.75
	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 Ma	ax): 665 bar/sec

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

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

10.2 <u>Chemical stability</u>

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** <u>Incompatible materials</u> Strong oxidizing agents.
- **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



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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.	
Skin corrosion/irritation	*Adverse effect observed (irritating)	
	Cutaneous compatibility is very good. (dilution at 10% and 20%)	
Serious eye damage/irritation	*Adverse effects observed (irritating).	
	*No adverse effect observed (not sensitising)	
Respiratory/skin sensitization	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	*Azelaic acid is excreted through urine (mean of 76.9% of and distribution	
distribution	infused dose). Reported in HDSB, Bertuzzi A et al; Clin Pharmacokinet	
distribution	20 (5):411-9 (1991)	
	*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)	
Repeated dose toxicity	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.	
	*No adverse effect observed (negative)	
Gorm Coll mutagonicity	According to DSD (67/548/EEC) or CLP (1272/2008/EC) classification	
Germ Cell mutagenicity	criteria for genetic toxicity, fatty acids do not fulfill the criteria for	
	classification and thus a non-classification is warranted for this endpoint.	
Carcinogenicity	No further relevant information available.	
	*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	
Reproductive toxicity	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 (

*from ECHA webpage registration data

11.2 Information on toxicological effects Endocrine disrupting properties Substance is not listed.

SECTION 12: ECOLOGICAL INFORMATION

Name	Azelaic Acid CAS:123-99-9
12.1 Toxicity Aquatic toxicity	Based on available data, the classification criteria are not met. *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)



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	*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 bidodegradability studies w (category approach: fatty acids). Degree of days (closed bottle test, OECD 301D). The chromophores that absorb at wavelengths expected to be susceptible to direct photoly	degradability: 105 % in 30 substance does not contain > 290 nm and therefore is not
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 poter aquatic organisms is low.	ntial for bioconcentration in
12.4 Mobility in soil	*log Koc: 1.02 (prediction KOCWIN v. 2.00, If released to soil, the substance is expected based upon an estimated Koc of 10.57. The pKa of the substance is 4.55, indicating almost entirely in the anion form in the envi do not adsorb more strongly to soils contain than their neutral counterparts.	ed to have moderate mobility g that this compound will exist ronment and anions generally
12.5 Results of PBT and vPvB	PBT: Not applicable	
assessment	vPvB: Not applicable	
12.6 Endocrine disrupting	The product does not contain substances v	vith endocrine disrupting
properties	properties.	
12.7 Other adverse effects	Water hazard class 1 (German Regulation) hazardous for water Do not allow undiluted product or large qua water, water course or sewage system.	. ,

*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

- 13.2 Uncleaning packaging Recommendation **Recommended cleansing agents**

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

Irritant - skin irritation and eye damage

SECTION 14: TRANSPORT INFORMATION

14.1 UN number or ID number

ADR/RID	Not applicable
ADN	Not applicable
IMDG	Not applicable
ΙΑΤΑ	Not applicable



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- 14.2 UN proper shipping name ADR/RID Not applicable Not applicable ADN Not applicable IMDG IATA Not applicable 14.3 Transport hazard class(es) ADR/RID Not applicable Not applicable ADN IMDG Not applicable IATA Not applicable 14.4 Packing group
- ADR/RID Not applicable ADN Not applicable IMDG Not applicable IATA Not applicable
- 14.5Environmental hazard
Marine pollutantNo
- 14.6
 Special precautions for user
 Not applicable
- 14.7 <u>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</u> Not applicable
- **14.8** ICAO/IATA DGR Not regulated as dangerous good
- Maritime transport in bulk according to IMO instruments
 Not applicable

 UN "Model Regulation"
 Not applicable

SECTION 15: REGULATORY INFORMATION

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

Name	Azelaic Acid CAS:123-99-9	
Inventory - United States - Toxic Substances Control Act (TSCA)	Y	
Inventory - Canada - Domestic Substances List (DSL)	Y	
Inventory - Canada Non-Domestic Substances List (NDSL)	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	



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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	Ν

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.

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 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