

Nifedipine Apollo Scientific

Part Number: OR905666 Version No: 1.1 Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

Chemwatch Hazard Alert Code: 2

Issue Date: **18/05/2023** Print Date: **18/05/2023** S.REACH.GB-NIR.EN

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

1.1. Product Identifier

Product name	Nifedipine
Chemical Name	nifedipine
Synonyms	Not Available
Chemical formula	C17-H18-N2-O6
Other means of identification	Not Available
CAS number	21829-25-4*
EC number	244-598-3

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

Relevant identified uses	Not Available
Uses advised against	No specific uses advised against are identified.

1.3. Details of the manufacturer or supplier of the safety data sheet

Registered company name	Apollo Scientific	Apollo Scientific Itd
Address	Whitefield Road, Bredbury SK62QR United Kingdom	Whitefield Road Not Available SK6 2QR United Kingdom (NI)
Telephone	01614060505	+44(0) 161 406 0505
Fax	0161 406 0506	Not Available
Website	http://www.apolloscientific.co.uk/	apolloscientific.co.uk
Email	sales@apolloscientific.co.uk	sales@apolloscientific.co.uk

1.4. Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	Not Available
Other emergency telephone numbers	Not Available

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments [1]	
Legend:	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

2.2. Label elements

Hazard pictogram(s)



Signal word

Warning

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Hazard statement(s)

H302 Harmful if swallowed.

Supplementary Phrases

Not Applicable

Precautionary statement(s) Prevention

P264	Wash all exposed external body areas thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.

Precautionary statement(s) Response

· · · · · · · · · · · · · · · · · · ·		
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell.	
P330	Rinse mouth.	

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

P501 Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

2.3. Other hazards

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 Composition / information on ingredients

3.1.Substances

1. CAS No 2.EC No 3.Index No 4.REACH No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
Not Available Not Available Not Available Not Available Not Available	100	Nifedipine	Sensitisation (Skin) Category 1; H317 [1]	Not Available	Not Available

Legend:

1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties

3.2.Mixtures

See 'Information on ingredients' in section 3.1

SECTION 4 First aid measures

4.1. Description of first aid measures

Eye Contact	If this product comes in contact with eyes: • Wash out immediately with water. • If irritation continues, seek medical attention. • Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs: Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	 If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary.
Ingestion	 Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

4.2 Most important symptoms and effects, both acute and delayed

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

5.1. Extinguishing media

- ▶ There is no restriction on the type of extinguisher which may be used.
- ▶ Use extinguishing media suitable for surrounding area.

5.2. Special hazards arising from the substrate or mixture

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Fire Incompatibility	None known.
5.3. Advice for firefighters	
Fire Fighting	
Fire/Explosion Hazard	Non combustible.

▶ Not considered a significant fire risk, however containers may burn.

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

Minor Spills	 Clean up all spills immediately. Avoid breathing vapours/ aerosols or dusts and avoid contact with skin and eyes. Place in a suitable, labelled container for waste disposal.
Major Spills	 Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Control personal contact with the substance, by using protective equipment. Prevent spillage from entering drains, sewers or water courses. Recover product wherever possible. Put residues in labelled containers for disposal. If contamination of drains or waterways occurs, advise emergency services.

6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

7.1. Precautions for safe handling

Safe handling	 Limit all unnecessary personal contact. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Use good occupational work practice. Observe manufacturer's storage and handling recommendations contained within this SDS. Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
Fire and explosion protection	See section 5
Other information	

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	 Polyethylene or polypropylene container. Packing as recommended by manufacturer. Check all containers are clearly labelled and free from leaks. 		
Storage incompatibility	Avoid contamination of water, foodstuffs, feed or seed. None known		
Hazard categories in accordance with Regulation (EC) No 1272/2008	Not Available		
Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of	Not Available		

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

Ingredient	DNELs	PNECs

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	Exposure Pattern Worker	Compartment
Not Available	Not Available	Not Available

^{*} Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not Available						

Not Applicable

Emergency Limits

Ingredient	TEEL-1	TEEL-2		TEEL-3
Nifedipine	Not Available	Not Available		Not Available
Ingredient	Original IDLH		Revised IDLH	
Nifedinine	Not Available		Not Available	

8.2. Exposure controls

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.

Employers may need to use multiple types of controls to prevent employee overexposure.

General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, degreasing etc., evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)

8.2.1. Appropriate engineering controls

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood - local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

8.2.2. Individual protection measures, such as personal











protective equipment

Eye and face protection

- ▶ Safety glasses with side shields
- Chemical goggles

Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or

Skin protection

national equivalent] See Hand protection below

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Hands/feet protection	Wear general protective gloves, eg. light weight rubber gloves.
Body protection	See Other protection below
Other protection	No special equipment needed when handling small quantities. OTHERWISE: Overalls. Barrier cream. Eyewash unit.

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the computer-

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Material	СРІ
PE/EVAL/PE	A

- * CPI Chemwatch Performance Index
- A: Best Selection
- B: Satisfactory; may degrade after 4 hours continuous immersion
- C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

8.2.3. Environmental exposure controls

See section 12

SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

Respiratory protection

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

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Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	-	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO =

Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

Appearance	Not Available			
Physical state	Powder	Relative density (Water = 1)	Not Available	
Odour	Not Available	Partition coefficient n-octanol / water	Not Available	

Physical state	Powder	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	173-177	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Available
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

9.2. Other information

Not Available

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SECTION 10 Stability and reactivity

10.1.Reactivity	See section 7.2
10.2. Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

SECTION 11 Toxicological information

11.1. Information on toxicological effects

11.1. Information on toxicologi	cal effects		
Inhaled	The material is not thought to produce adverse health et models). Nevertheless, good hygiene practice requires to occupational setting.		•
Ingestion	The material has NOT been classified by EC Directives corroborating animal or human evidence.	or other classification systems as "h	armful by ingestion". This is because of the lack of
Skin Contact	The material is not thought to produce adverse health el models). Nevertheless, good hygiene practice requires t setting.		
Еуе	Although the material is not thought to be an irritant (as characterised by tearing or conjunctival redness (as with		ontact with the eye may produce transient discomfort
Chronic	Long-term exposure to the product is not thought to produce models); nevertheless exposure by all routes should be		ealth (as classified by EC Directives using animal
	TOXICITY	IRRITATION	
Nifedipine	Oral (Cat) LD50; 100 mg/kg ^[2]	Not Available	
Legend:	Value obtained from Europe ECHA Registered Subst. specified data extracted from RTECS - Register of Toxic	•	ned from manufacturer's SDS. Unless otherwise
Acute Toxicity	✓	Carcinogenicity	×
Skin Irritation/Corrosion	×	Reproductivity	×
Serious Eye Damage/Irritation	×	STOT - Single Exposure	×
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	x

Legend:

X – Data either not available or does not fill the criteria for classification

Data available to make classification

Aspiration Hazard

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

Mutagenicity

No evidence of endocrine disrupting properties were found in the current literature.

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11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

	Endpoint	Test Duration (hr)	Species	Value	Source
Nifedipine	EC0(ECx)	48h	Crustacea	>=3.88mg/l	1
	LC50	96h	Fish	>=5.77mg/l	1
Legend:	Ecotox databa		ed Substances - Ecotoxicological Information - Aqua ard Assessment Data 6. NITE (Japan) - Bioconcent		

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

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12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

12.4. Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

12.5. Results of PBT and vPvB assessment

	Р	В	Т
Relevant available data	Not Available	Not Available	Not Available
PBT	X	×	×
vPvB	×	×	×
PBT Criteria fulfilled?			No
vPvB			No

12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.

SECTION 13 Disposal considerations

13.1. Waste treatment methods

10.11. Waste treatment methods	
Product / Packaging disposal	 Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill. Recycle containers if possible, or dispose of in an authorised landfill.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 Transport information

Labels Required

Labolo Moquilou	
Marine Pollutant	NO
HAZCHEM	Not Applicable

Land transport (ADR): NOT RE	GULATED FOR TRANSPORT	OF DANGEROUS GOODS
14.1. UN number or ID number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard	Class Not Applical	ble
class(es)	Subsidiary risk Not Applicat	ble
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
	Hazard identification (Kemler)	Not Applicable
	Classification code	Not Applicable
14.6. Special precautions for	Hazard Label	Not Applicable
user	Special provisions	Not Applicable
	Limited quantity	Not Applicable
	Tunnel Restriction Code	Not Applicable

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	ICAO/IATA Class ICAO / IATA Subrisk	Not Applicable Not Applicable

	ERG Code Not Applicable	
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
	Special provisions	Not Applicable
14.6. Special precautions for user	Cargo Only Packing Instructions	Not Applicable
	Cargo Only Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Packing Instructions	Not Applicable
	Passenger and Cargo Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Limited Quantity Packing Instructions	Not Applicable
	Passenger and Cargo Limited Maximum Qty / Pack	Not Applicable

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable
14.2. UN proper shipping name	Not Applicable
14.3. Transport hazard class(es)	IMDG Class Not Applicable IMDG Subrisk Not Applicable
14.4. Packing group	Not Applicable
14.5. Environmental hazard	Not Applicable
14.6. Special precautions for user	EMS Number Not Applicable Special provisions Not Applicable Limited Quantities Not Applicable

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable
14.2. UN proper shipping name	Not Applicable
14.3. Transport hazard class(es)	Not Applicable Not Applicable
14.4. Packing group	Not Applicable
14.5. Environmental hazard	Not Applicable
14.6. Special precautions for user	Classification code Not Applicable Special provisions Not Applicable Limited quantity Not Applicable Equipment required Not Applicable Fire cones number Not Applicable

14.7. Maritime transport in bulk according to IMO instruments

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
Nifedipine	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
Nifedipine	Not Available

SECTION 15 Regulatory information

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

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

Information according to 2012/18/EU (Seveso III):

Seveso Category Not Available

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For further information please look at the Chemical Safety Assessment and Exposure Scenarios prepared by your Supply Chain if available.

ECHA SUMMARY

Not Applicable

National Inventory Status

National Inventory Status	
National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	Yes
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - FBEPH	Yes
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

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Full text Risk and Hazard codes

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered. For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

Definitions and abbreviations

PC-TWA: Permissible Concentration-Time Weighted Average

PC-STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit。

IDLH: Immediately Dangerous to Life or Health Concentrations

ES: Exposure Standard

OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit Of Detection

OTV: Odour Threshold Value

BCF: BioConcentration Factors

BEI: Biological Exposure Index

AIIC: Australian Inventory of Industrial Chemicals

DSL: Domestic Substances List

NDSL: Non-Domestic Substances List

IECSC: Inventory of Existing Chemical Substance in China

EINECS: European INventory of Existing Commercial chemical Substances

ELINCS: European List of Notified Chemical Substances

NLP: No-Longer Polymers

ENCS: Existing and New Chemical Substances Inventory

KECI: Korea Existing Chemicals Inventory

NZIoC: New Zealand Inventory of Chemicals

PICCS: Philippine Inventory of Chemicals and Chemical Substances

TSCA: Toxic Substances Control Act

TCSI: Taiwan Chemical Substance Inventory

INSQ: Inventario Nacional de Sustancias Químicas

NCI: National Chemical Inventory

FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	Classification Procedure
Acute Toxicity (Oral) Category 4, H302	Expert judgement

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