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SAFETY DATA SHEET

Invivoscribe® ABI Assays

Catalog Number	Description
11000031	*IGH* + *IGK* B-Cell Clonality Assay for ABI Fluorescence Detection
11000041	*IGH* + *IGK* B-Cell Clonality Assay MegaKit for ABI Fluorescence Detection
11010061	*IGH* Gene Clonality Assay for ABI Fluorescence Detection
11010081	*IGH* Gene Clonality Assay MegaKit for ABI Fluorescence Detection
11010051	*IGH* Gene Rearrangement Assay for ABI Fluorescence Detection
11010071	*IGH* Gene Rearrangement Assay MegaKit for ABI Fluorescence Detection
11020021	*IGK* Gene Clonality Assay for ABI Fluorescence Detection
11020031	*IGK* Gene Clonality Assay MegaKit for ABI Fluorescence Detection
11030011	*IGL* Gene Clonality Assay for ABI Fluorescence Detection
11030021	*IGL* Gene Clonality Assay MegaKit for ABI Fluorescence Detection
12050011	*TCRB* Gene Clonality Assay for ABI Fluorescence Detection
12050021	*TCRB* Gene Clonality Assay MegaKit for ABI Fluorescence Detection
12060011	*TCRD* Gene Clonality Assay for ABI Fluorescence Detection
12060021	*TCRD* Gene Clonality Assay MegaKit for ABI Fluorescence Detection
12070051	T-cell Receptor Gamma Gene Rearrangement Assay for ABI Fluorescence Detection
12070101	T-cell Receptor Gamma Gene Rearrangement Assay 2.0 for ABI Fluorescence Detection
12070111	T-cell Receptor Gamma Gene Rearrangement Assay 2.0 MegaKit for ABI Fluorescence Detection
13100031	*BCR/ABL* t(9;22) Translocation Assay for ABI Fluorescence Detection
13110011	*PML/RARA* t(15;17) Translocation Assay for ABI Fluorescence Detection
14120031	*FLT3* Mutation Assay for ABI Fluorescence Detection
51010031	*IGH* Somatic Hypermutation Assay v2.0 for ABI Fluorescence Detection
51010041	*IGH* Somatic Hypermutation Assay MegaKit v2.0 for ABI Fluorescence Detection

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 as amended by Commission Regulation (EU) 2020/878 and Regulation (EC) No. 1272/2008

Issuing Date 27-Apr-2023 **Revision Date** 27-Apr-2023 **Revision Number** 1

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

1.1. Product identifier

Product Code(s)	Product Name	Synonyms
40880190	IVS-0004 Clonal Control DNA	None
40880370	IVS-0007 Clonal Control DNA	None
40880430	IVS-0008 Clonal Control DNA	None
40880490	IVS-0009 Clonal Control DNA	None
40880550	IVS-0010 Clonal Control DNA	None
40880730	IVS-0013 Clonal Control DNA	None
40880970	IVS-0017 Clonal Control DNA	None
40881090	IVS-0019 Clonal Control DNA	None
40881210	IVS-0021 Clonal Control DNA	None
40881390	IVS-0024 Clonal Control DNA	None
40881690	IVS-0029 Clonal Control DNA	None
40881750	IVS-0030 Clonal Control DNA	None
40881810	IVS-0031 Clonal Control DNA	None
40883320	5% *TCRG* Positive Control DNA	None

Pure substance/mixture Mixture

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

Recommended use Assay reagent

Uses advised against For professional use only

1.3. Details of the supplier of the safety data sheet

Importer
Invivoscribe Technologies
Zeppelinstrasse 1
85399 Hallbergmoos
Germany
Phone: +49 89 904 299 800

Supplier
Invivoscribe, Inc.
10222 Barnes Canyon Rd
Bldg. 1
San Diego, CA 92121
Phone: +1 858-224-6600

Distributor
Invivoscribe Technologies, SARL
c/o Ficorec Domiciliation Services
132, Boulevard Michelet
Hall Nord – 5ème étage
13008 Marseille
FRANCE
Tel: +33 (0)4 42 01 78 10

For further information, please contact

E-mail address customerservice@invivoscribe.com

1.4. Emergency telephone number

Emergency telephone +49 89 904 299 800 (M-F 8:00 – 16:30 CET)

Emergency telephone - §45 - (EC)1272/2008	
Europe	**112**

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

SECTION 2: Hazards identification

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

2.2. Label elements

Hazard statements

Not classified.

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

2.3. Other hazards

No information available.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

SECTION 3: Composition/information on ingredients

3.1 Substances

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation Remove to fresh air. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact Wash skin with soap and water. Get medical attention if symptoms occur.

Ingestion Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth. Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms None known.

Effects of Exposure No information available.

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

Note to physicians Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical No information available.

5.3. Advice for firefighters

SECTION 5: Firefighting measures

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Dam up. Soak up with inert absorbent material. Take up mechanically, placing in appropriate containers for disposal.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections	See section 8 for more information See section 13 for more information

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.
Storage class (TRGS 510)	Storage class 10.

7.3. Specific end use(s)

Specific use(s)	The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region-specific regulatory bodies.

Derived No Effect Level (DNEL) - Workers	No information available.
Derived No Effect Level (DNEL) - General Public	No information available.
Predicted No Effect Concentration (PNEC)	No information available.

8.2. Exposure controls

Engineering controls	Showers Eyewash stations Ventilation systems.

SECTION 8: Exposure controls/personal protection

Personal protective equipment	
Eye/face protection	Wear safety glasses with side shields (or goggles). Eye protection must conform to standard EN 166.
Hand protection	Wear suitable gloves. Gloves must conform to standard EN 374.
Skin and body protection	Wear suitable protective clothing. (EN ISO 6529).
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
Environmental exposure controls	No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Liquid
Color	Colorless
Odor	Odorless
Odor threshold	No information available

Property	Values	Remarks • Method
Melting point / freezing point		No data available
Initial boiling point and boiling range		No data available
Flammability		No data available
Flammability Limit in Air		No data available
Upper flammability or explosive limits		No data available
Lower flammability or explosive limits		No data available
Flash point		No data available
Autoignition temperature		No data available
Decomposition temperature		No data available
pH		No data available
pH (as aqueous solution)		No data available
Kinematic viscosity		No data available
Dynamic viscosity		No data available
Water solubility		No data available
Solubility(ies)		No data available
Partition coefficient		No data available
Vapor pressure		No data available
Relative density		No data available
Bulk density		No data available
Liquid density		No data available
Relative vapor density		No data available
Particle characteristics		No data available
Particle size		No data available
Particle size distribution		No data available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Not applicable

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity None under normal use conditions.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available. Contact with eyes may cause irritation.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms None known.

Acute toxicity

Numerical measures of toxicity

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

Component Information

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitization Based on available data, the classification criteria are not met.

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

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

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

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.

SECTION 11: Toxicological information

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

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

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment The product does not contain any substance(s) classified as PBT or vPvB.

12.6. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

12.7. Other adverse effects

Other adverse effects No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

Waste codes / waste designations according to EWC / AVV According to the European Waste Catalog, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

SECTION 14: Transport information

IMDG Not regulated

14.1 UN number or ID number Not regulated

14.2 UN proper shipping name Not regulated

14.3 Transport hazard class(es) Not regulated

14.4 Packing group Not applicable

14.5 Environmental hazards Not applicable

14.6 Special Precautions for Users

Special Provisions None

14.7 Maritime transport in bulk according to IMO instruments No information available

SECTION 14: Transport information

RID		Not regulated
14.1	**UN number**	Not regulated
14.2	**UN proper shipping name**	Not regulated
14.3	**Transport hazard class(es)**	Not regulated
14.4	**Packing group**	Not applicable
14.5	**Environmental hazards**	Not applicable
14.6	**Special Precautions for Users**	
	Special Provisions	None
ADR		Not regulated
14.1	**UN number or ID number**	Not regulated
14.2	**UN proper shipping name**	Not regulated
14.3	**Transport hazard class(es)**	Not regulated
14.4	**Packing group**	Not applicable
14.5	**Environmental hazards**	Not applicable
14.6	**Special Precautions for Users**	
	Special Provisions	None
IATA		Not regulated
14.1	**UN number or ID number**	Not regulated
14.2	**UN proper shipping name**	Not regulated
14.3	**Transport hazard class(es)**	Not regulated
14.4	**Packing group**	Not applicable
14.5	**Environmental hazards**	Not applicable
14.6	**Special Precautions for Users**	
	Special Provisions	None
	Note:	None

SECTION 15: Regulatory information

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

National regulations

Germany

Water hazard class (WGK) non-hazardous to water (nwg)

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:
This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants
Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Not applicable

International Inventories

Contact supplier for inventory compliance status

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend

ATE: Acute Toxicity Estimate

SVHC: Substances of Very High Concern for Authorization:

PBT: Persistent, Bioaccumulative, and Toxic (PBT) Substances

vPvB: Very Persistent and very Bioaccumulative (vPvB) Substances

Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
SCBA	Self-contained breathing apparatus		

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	On basis of test data
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)

European Chemicals Agency (ECHA) (ECHA_API)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

SECTION 16: Other information

NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
United States of America National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Issuing Date	27-Apr-2023
Revision Date	27-Apr-2023
Revision Note	Initial Release.

This safety data sheet complies with the requirements of Commission Regulation (EU) 2020/878 of 18 June 2020 amending Regulation (EC) No. 1907/2006

Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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

1.1. Product identifier

Product Code(s)	Product Name	Synonyms
20960011	Amplification Control - 6FAM for ABI Fluorescence Detection	None
20960021	Specimen Control Size Ladder - 6FAM for ABI Fluorescence Detection	None
21010011	*IGH* Tube A - 6FAM for ABI Fluorescence Detection	None
21010031	*IGH* Tube C - HEX for ABI Fluorescence Detection	None
21010041	*IGH* Tube D - HEX for ABI Fluorescence Detection	None
21010051	*IGH* Tube E - 6FAM Fluorescence Detection	None
21010061	*IGH* Framework 1 (FR1) - 6FAM for ABI Fluorescence Detection	None
21010081	*IGH* Framework 3 (FR3) - HEX for ABI Fluorescence Detection	None
21010091	*IGH* Framework 2 (FR2) - 6FAM for ABI Fluorescence Detection	None
21010101	*IGH* Tube B - 6FAM for ABI Fluorescence Detection	None
21010171	Hypermutation Mix 1 v2.0 - 6FAM for ABI Fluorescence Detection	None
21010181	Hypermutation Mix 2 v2.0 6FAM for ABI Fluorescence Detection	None
21020011	*IGK* Tube A - 6FAM for ABI Fluorescence Detection	None
21020021	*IGK* Tube B - 6FAM for ABI Fluorescence Detection	None
21030011	*IGL* Tube - 6FAM for ABI Fluorescence Detection	None
22050011	*TCRB* Tube A - 6FAM & HEX for ABI Fluorescence Detection	None
22050021	*TCRB* Tube B - 6FAM for ABI Fluorescence Detection	None
22050031	*TCRB* Tube C - 6FAM & HEX for ABI Fluorescence Detection	None
22060011	*TCRD* Tube - 6FAM & HEX for ABI Fluorescence	None
22070021	T Cell Receptor Gamma Mix 2 - HEX for ABI Fluorescence Detection	None
22070071	T-Cell Receptor Gamma Mix 1 - 6FAM for ABI Fluorescence Detection	None
22070091	*TCRG* - 6FAM	None
23100010	*BCR/ABL* t(9;22) Mix 1a for Gel Detection	None
23100020	*BCR/ABL* t(9;22) Mix 2a for Gel Detection	None
23100030	*BCR/ABL* t(9;22) Mix 3a for Gel Detection	None
23100041	*BCR/ABL* t(9;22) Mix 1b - HEX for ABI Fluorescence Detection	None
23100051	*BCR/ABL* t(9;22) Mix 2b - HEX for ABI Fluorescence Detection	None
23100061	*BCR/ABL* t(9;22) Mix 2c - HEX for ABI Fluorescence Detection	None
23100071	*BCR/ABL* t(9;22) Mix 3b - 6FAM for ABI Fluorescence Detection	None
23100081	*BCR/ABL* t(9;22) Mix 3c - 6FAM for ABI Fluorescence Detection	None
23100101	*BCR/ABL* t(9;22) Mix 3d - 6FAM for ABI Fluorescence Detection	None
23110011	*PML/RARA* t(15;17) Mix 1 - HEX for ABI Fluorescence Detection	None
23110020	*PML/RARA* t(15;17) Mix 2a for Gel Detection	None
23110031	*PML/RARA* t(15;17) Mix 2b - HEX for ABI Fluorescence Detection	None
23110041	*PML/RARA* t(15;17) Mix 2c - HEX for ABI Fluorescence Detection	None
24120011	*FLT3* ITD Master Mix - 6FAM & HEX for ABI Fluorescence Detection	None
24120031	*FLT3* D835 Master Mix - 6FAM for ABI Fluorescence Detection	None
30000000	Primer Hypermutation 100 µM - Unlabeled	None
31010380	*IGH* JH Primer 100 µM - Unlabeled	None

Pure substance/mixture Mixture

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

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

Recommended use Assay reagent

Uses advised against For professional use only

1.3. Details of the supplier of the safety data sheet

Importer
Invivoscribe Technologies
Zeppelinstrasse 1
85399 Hallbergmoos
Germany
Phone: +49 89 904 299 800

Supplier
Invivoscribe, Inc.
10222 Barnes Canyon Rd
Bldg. 1
San Diego, CA 92121
Phone: +1 858-224-6600

Distributor
Invivoscribe Technologies, SARL
c/o Ficorec Domiciliation Services
132, Boulevard Michelet
Hall Nord – 5ème étage
13008 Marseille
FRANCE
Tel: +33 (0)4 42 01 78 10

For further information, please contact

E-mail address customerservice@invivoscribe.com

1.4. Emergency telephone number

Emergency telephone +49 89 904 299 800 (M-F 8:00 – 16:30 CET)

Emergency telephone - §45 - (EC)1272/2008	
Europe	**112**

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

Hazard statements

Not classified.

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

2.3. Other hazards

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Dimethyl sulfoxide 67-68-5	1-5	No data available	200-664-3	[C]	-	-	-

Classification according to Regulation (EC) No. 1272/2008 [CLP] - Notes

[C] - Components with occupational exposure limits and/or biological occupational exposure limits requiring monitoring

Full text of H- and EUH-phrases: see section 16

SECTION 3: Composition/information on ingredients

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Dimethyl sulfoxide 67-68-5	28300	40000	5.3353	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation Remove to fresh air. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water, also under the eyelids. Get medical attention if symptoms occur.

Skin contact Wash skin with soap and water. Get medical attention if symptoms occur.

Ingestion Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth. Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms None known.

Effects of Exposure No information available.

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

Note to physicians Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Dam up. Soak up with inert absorbent material. Take up mechanically, placing in appropriate containers for disposal.

SECTION 6: Accidental release measures

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information See section 13 for more information

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

Storage class (TRGS 510) Storage class 10.

7.3. Specific end use(s)

Specific use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Dimethyl sulfoxide 67-68-5	-	TWA: 50 ppm TWA: 160 mg/m³ H*	-	-	-
Chemical name	**Cyprus**	**Czech Republic**	**Denmark**	**Estonia**	**Finland**
Dimethyl sulfoxide 67-68-5	-	-	TWA: 50 ppm TWA: 160 mg/m³ STEL: 100 ppm STEL: 320 mg/m³	TWA: 50 ppm TWA: 150 mg/m³ STEL: 150 ppm STEL: 500 mg/m³ A*	TWA: 50 ppm iho*
Chemical name	**France**	**Germany TRGS**	**Germany DFG**	**Greece**	**Hungary**
Dimethyl sulfoxide 67-68-5	-	TWA: 50 ppm TWA: 160 mg/m³ H*	TWA: 50 ppm TWA: 160 mg/m³ Peak: 100 ppm Peak: 320 mg/m³ *	-	-
Chemical name	**Ireland**	**Italy MDLPS**	**Italy AIDII**	**Latvia**	**Lithuania**
Dimethyl sulfoxide 67-68-5	-	-	-	-	O* TWA: 50 ppm TWA: 150 mg/m³ STEL: 150 ppm STEL: 500 mg/m³
Chemical name	**Portugal**	**Romania**	**Slovakia**	**Slovenia**	**Spain**
Dimethyl sulfoxide 67-68-5	-	-	-	TWA: 160 mg/m³ TWA: 50 ppm STEL: 100 ppm STEL: 320 mg/m³ K*	-

Chemical name	Sweden	Switzerland	United Kingdom

SECTION 8: Exposure controls/personal protection

Dimethyl sulfoxide 67-68-5	NGV: 50 ppm NGV: 150 mg/m³ Vägledande KGV: 150 ppm Vägledande KGV: 500 mg/m³ H*	TWA: 50 ppm TWA: 160 mg/m³ STEL: 100 ppm STEL: 320 mg/m³ H*	-

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) - Workers

Chemical name	Oral	Dermal	Inhalation
Dimethyl sulfoxide 67-68-5	-	200 mg/kg bw/day [4] [6]	484 mg/m³ [4] [6] 265 mg/m³ [5] [6]

Notes

[4] Systemic health effects.

[5] Local health effects.

[6] Long term.

[7] Short term.

Derived No Effect Level (DNEL) - General Public

Chemical name	Oral	Dermal	Inhalation
Dimethyl sulfoxide 67-68-5	60 mg/kg bw/day [4] [6]	-	120 mg/m³ [4] [6] 47 mg/m³ [5] [6]

Notes

[4] Systemic health effects.

[5] Local health effects.

[6] Long term.

[7] Short term.

Predicted No Effect Concentration (PNEC)

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Dimethyl sulfoxide 67-68-5	17 mg/L	-	1.7 mg/L	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Dimethyl sulfoxide 67-68-5	13.4 mg/kg sediment dw	-	11 mg/L	3.02 mg/kg soil dw	0.7 g/kg food

8.2. Exposure controls

Engineering controls

Showers
Eyewash stations
Ventilation systems.

Personal protective equipment

Eye/face protection

Wear safety glasses with side shields (or goggles). Eye protection must conform to standard EN 166.

Hand protection

Wear suitable gloves. Gloves must conform to standard EN 374.

Skin and body protection

Wear suitable protective clothing (EN ISO 6529).

Respiratory protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

SECTION 8: Exposure controls/personal protection

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance Clear liquid

Physical state Liquid

Color Colorless. Light blue, light yellow, light pink. or light orange

Odor Odorless

Odor threshold No information available

Property	Values	Remarks • Method
Melting point / freezing point		No data available
Initial boiling point and boiling range		No data available
Flammability		No data available
Flammability Limit in Air		
Upper flammability or explosive limits		No data available
Lower flammability or explosive limits		No data available
Flash point		No data available
Autoignition temperature		No data available
Decomposition temperature		No data available
pH	7 - 9.5	No data available
pH (as aqueous solution)		No data available
Kinematic viscosity		No data available
Dynamic viscosity		No data available
Water solubility		No data available
Solubility(ies)		No data available
Partition coefficient		No data available
Vapor pressure		No data available
Relative density		No data available
Bulk density		No data available
Liquid Density		No data available
Relative vapor density		No data available
Particle characteristics		
Particle Size		No data available
Particle Size Distribution		No data available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Not applicable

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity None under normal use conditions.

10.2. Chemical stability

SECTION 10: Stability and reactivity

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available. Contact with eyes may cause irritation.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms None known.

Acute toxicity

Numerical measures of toxicity

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

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Dimethyl sulfoxide	= 28300 mg/kg (Rat)	= 40000 mg/kg (Rat)	> 5.33 mg/L (Rat) 4 h

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitization Based on available data, the classification criteria are not met.

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

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

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

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

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

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

11.2. Information on other hazards

SECTION 11: Toxicological information

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

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

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Dimethyl sulfoxide 67-68-5	-	LC50: =34000mg/L (96h, Pimephales promelas) LC50: 33 - 37g/L (96h, Oncorhynchus mykiss) LC50: >40g/L (96h, Lepomis macrochirus) LC50: =41.7g/L (96h, Cyprinus carpio)	-	-

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Component Information

Chemical name	Partition coefficient
Dimethyl sulfoxide	-1.35

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment The product does not contain any substance(s) classified as PBT or vPvB.

Chemical name	PBT and vPvB assessment
Dimethyl sulfoxide 67-68-5	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

12.7. Other adverse effects

Other adverse effects No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

Waste codes / waste designations according to EWC / AVV According to the European Waste Catalog, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

SECTION 14: Transport information

IMDG		Not regulated
14.1	**UN number or ID number**	Not regulated
14.2	**UN proper shipping name**	Not regulated
14.3	**Transport hazard class(es)**	Not regulated
14.4	**Packing group**	Not applicable
14.5	**Environmental hazards**	Not applicable
14.6	**Special Precautions for Users**	
	Special Provisions	None
14.7	**Maritime transport in bulk according to IMO instruments**	No information available

RID		Not regulated
14.1	**UN number**	Not regulated
14.2	**UN proper shipping name**	Not regulated
14.3	**Transport hazard class(es)**	Not regulated
14.4	**Packing group**	Not applicable
14.5	**Environmental hazards**	Not applicable
14.6	**Special Precautions for Users**	
Special Provisions		None

ADR		Not regulated
14.1	**UN number or ID number**	Not regulated
14.2	**UN proper shipping name**	Not regulated
14.3	**Transport hazard class(es)**	Not regulated
14.4	**Packing group**	Not applicable
14.5	**Environmental hazards**	Not applicable
14.6	**Special Precautions for Users**	
	Special Provisions	None

IATA		Not regulated
14.1	**UN number or ID number**	Not regulated
14.2	**UN proper shipping name**	Not regulated
14.3	**Transport hazard class(es)**	Not regulated
14.4	**Packing group**	Not applicable
14.5	**Environmental hazards**	Not applicable
14.6	**Special Precautions for Users**	
	Special Provisions	None

Note: None

SECTION 15: Regulatory information

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

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
Dimethyl sulfoxide 67-68-5	RG 84

Germany

Water hazard class (WGK) non-hazardous to water (nwg)

SECTION 15: Regulatory information

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Dimethyl sulfoxide - 67-68-5	75.	-

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

Contact supplier for inventory compliance status

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend

ATE: Acute Toxicity Estimate

SVHC: Substances of Very High Concern for Authorization:

PBT: Persistent, Bioaccumulative, and Toxic (PBT) Substances

vPvB: Very Persistent and very Bioaccumulative (vPvB) Substances

Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
SCBA	Self-contained breathing apparatus		

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	On basis of test data
Reproductive toxicity	Calculation method

SECTION 16: Other information

STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
European Chemicals Agency (ECHA) (ECHA_API)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine’s PubMed database (NLM PUBMED)
United States of America National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

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Disclaimer

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End of Safety Data Sheet