SESLHD PROCEDURE COVER SHEET

NAME OF DOCUMENT	Safe Handling and Management of Monoclonal Antibodies
TYPE OF DOCUMENT	Procedure
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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director, People and Culture
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FUNCTIONAL GROUP(S)	Medicine Nursing and Midwifery Pharmaceutical Workplace Health and Safety
KEY TERMS	Monoclonal Antibodies, MABs, Cytotoxic, Occupational Exposure
SUMMARY	The procedure has been developed to ensure processes are in place to manage the potential risk to workers health when using Monoclonal Antibodies in the workplace.

1. POLICY STATEMENT

The use of Monoclonal antibodies (MABs) within cancer and other services has been expanding within our organisation and as they are not like traditional anticancer agents, MABs often do not fulfil the criteria for classification as cytotoxic or hazardous substances.

As there is currently limited research on the long term effects of MABs, SESLHD has decided to adopt the risk management principles outlined in Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel.

For additional information the Safework NSW Cytotoxic Drugs and Related Waste – Risk Management guide should also be referenced.

The procedure is intended to be used by workers who are involved in the handling of MABs and is applicable, but not limited to medical, pharmacy and nursing staff.

Relevant Ministry of Health Policy Documents include:

- PD2015_007 - Pharmaceutical – Preparation in NSW Public Health Facility Pharmacy Services
- PD2013_043 - Medication Handling in NSW Public Health Facilities
- PD2020_049 - Clinical and Related Waste Management for Health Services

2. DEFINITIONS

Monoclonal antibodies (MABs): A type of protein made in the laboratory that can bind to substances in the body, including cancer cells. A monoclonal antibody is made so that it binds to only one substance. Monoclonal antibodies are being used to treat some types of cancer and can be used alone or to carry drugs, toxins, or radioactive substances directly to cancer cells.

NHMRC : National Health and Medical Research Council

Personal Protective Equipment (PPE): Safety equipment provided to reduce the risk of exposure to specific MABs. Refer to **Monoclonal Antibody Risk Rating and Handling Precautions Guide** (appendix 1) for MAB specific PPE.

3. RESPONSIBILITIES

3.1 Clinical staff (medical officers, nurses, pharmacists) will:

- For existing MABs (at the time of writing) staff will check *Appendix 1 – Monoclonal Antibody Risk Rating and Handling Precautions Guide*, identify the risk level and PPE prior to handling or using the MAB.
- For new MABs staff will check Safety Data Sheets and/ or instructions provided by the drug manufacturer to identify the risk level and PPE prior to handling or using the MAB. In addition staff will escalate relevant information and additions to a senior manager.
- Report spills or any exposure to your manager and follow safety advice outlined by the manufacturer.
- Participate in occupational exposures program if handling High Risk MABs.

3.2 Line Managers will:

- Ensure workers are provided with appropriate PPE
- Where workers are required to handle MABs identified as high risk, arrange baseline assessments for health monitoring as per Occupational Exposures Procedure
- Report any new MABs that are not in the Monoclonal Risk Ratings to a Senior Manager.

3.3 Seniors Managers will:

- Support the program in place for Health monitoring and safe handling of MABs
- Report any new MABs that are not in SESLHD *Appendix 1 – Monoclonal Antibody Risk Rating and Handling Precautions Guide* to SESLHD Drug and Quality Use of Medicines Committee.

3.4 Drug and Quality Use of Medicines Committee will:

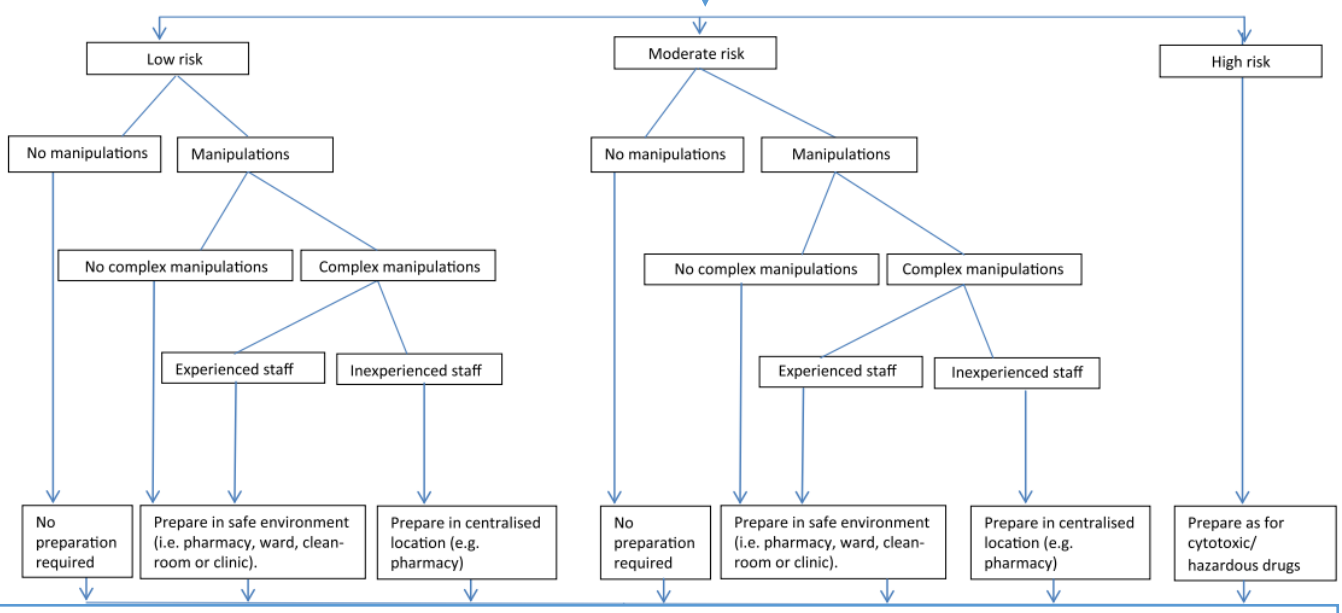
- Review newly identified MABs to ensure appropriate risk rating occurs and the suitable controls are documented and communicated to staff.

4. PROCEDURE

Occupational health and safety exposure risk as determined in Risk Matrix (refer to SESLHD Monoclonal Risk Rating)

Risk matrix		Risk of internalisation			
		None	*Low*	*Moderate*	*High*
Likelihood of Exposure	*Unlikely*		Oral	Inhalation† Mucosal†	
	Possible			Inhalation₸ Mucosal‡	
	Likely	Dermal			

†Limited to administration process. ₸Limited to preparation of powdered formulations. ‡Limited to preparation of doses.



Use sterile aseptic technique and recommended handling precautions for assigned OHS risk.

Exposure risk	Recommended handling precaution
No / Low risk	No additional precautions required, standard operating procedures† for both the preparation of doses for administration and administration.
Moderate risk	No additional precautions required, standard operating procedures for administration. Protective mask and eyewear, in addition to standard operating procedures for the preparation of doses for administration.
High risk	Treat like a cytotoxic or hazardous substance for both the preparation of doses for administration and administration.

†Standard operating procedures: standard operating procedure for parenterally administered pharmaceutical agents (i.e. aseptic technique according to the Australian Commission on Safety and Quality in Healthcare).

Report any spills or accidents with MABs to relevant line manager

4.1 Risk Identification and Controls

The **Monoclonal Antibody Risk Rating and Handling Precautions Guide** (Appendix 1) provides information on the risk level and handling precautions. Further information may be available from the Australian Injectable Drug Handbook (AIDH), Safety Data Sheets or instructions provided by the drug manufacturer. Whichever reference provides the highest level of controls are to be implemented.

4.2 Unlisted MABs

If the MAB is not listed in SESLHD monoclonal risk rating it is to be referred to the relevant line manager and the SESLHD Drug and Quality Use of Medicines Committee for review. If urgent administration is required, please contact the facility Pharmacy Department for the suggested risk rating and minimum handling precautions until formal advice provided.

4.3 Use of Personal Protective Equipment (PPE)

Current research indicates the most likely MAB absorption risks are through dermal absorption such as damaged skin (cuts, open wounds), inhalation or oral absorption. The likelihood of producing an aerosol with the required physical characteristics in the healthcare setting is limited.

The following recommendations have been adapted from the Clinical Oncology Society of Australia (COSA) and Cancer Pharmacists Group (CPG) position statement 2013 and the Australian Consensus Guidelines 2014. They apply to currently marketed monoclonal antibodies (MABs) except MABs conjugated to a cytotoxic agent, fusion protein or a radioisotope. These conjugated MABs are considered hazardous and should be prepared and administered following accepted cytotoxic safe handling precautions and regulations related to the handling of cytotoxics and radiopharmaceuticals.

- Dermal absorption of MABs across intact skin during dose preparation or administration is unlikely due to their high molecular weight, however, the use of gloves and effective hand hygiene are recommended to minimise risks of contamination and infection.
- A respirator mask and protective eyewear should be worn during dose preparation but are not mandated during the administration of MABs. However, they may be considered during the administration of intravenous formulations where dis/connecting administration lines may present a risk of aerosolisation.
- The use of gowns and/or coveralls are not warranted for either dose preparation or administration of MABs.
- Disposal of waste products including waste and/or bodily fluids of patients should be in accordance with the disposal of clinical waste i.e. not as cytotoxic waste.

For this reason the correct use of the appropriate PPE, is imperative in reducing the risk of exposure to workers. If the correct PPE is not available the relevant manager is to be notified immediately so it can be arranged before handling or administering a MAB.

4.4 Preparation of MABs

The preparation of low and moderate risk MABs require aseptic transfer techniques and are dispensed from pharmacy to the clinical area for preparation and administration (see Appendix 1).

ALL High Risk MABs must be prepared by a centralised service in the same safety cabinets as cytotoxic agents. Contact sterile manufacturing unit for further assistance.

Practical Application of Guideline Recommendations: Trastuzumab (Herceptin®)

1. Risk Matrix:
   i. Likelihood/Consequence of dermal absorption – likely/none
   ii. Likelihood/Consequence of oral absorption – unlikely/low
   iii. Likelihood/Consequence of inhalation absorption – possible /moderate during preparation of doses for administration and unlikely/moderate during administration.
   iv. Likelihood/Consequence of mucosal absorption – possible /moderate during preparation of doses for administration and unlikely/moderate during administration.

   Highest Risk Classification: **Moderate Risk** (see Appendix 1 for further details)

2. Flow Chart
   - **Moderate Risk** → **Manipulations Required** → **Vial Sharing** → **Prepare in centralised location** (e.g. pharmacy) → Use sterile aseptic technique and PPE as recommended
     or
   - **Moderate Risk** → **Manipulations Required** → **NO Vial Sharing** → Complex Manipulations → **Experienced Staff** → **Prepare in safe environment** (i.e. pharmacy, ward, clean-room or clinic) → Use sterile aseptic technique and PPE as recommended
     or
   - **Moderate Risk** → **Manipulations Required** → **NO Vial Sharing** → Complex Manipulations → **Inexperienced Staff** → **Prepare in centralised location** (e.g. pharmacy) → Use sterile aseptic technique and PPE as recommended

4.5 Disposal

Disposal of waste products (including patient waste) associated with low and moderate risk MABs should be in accordance with the policy directive PD2020_049 - Clinical and Related Waste Management for Health Services. This applies to waste production during preparation and administration, as well as patient waste. Disposal of high risk MABs is in accordance with cytotoxic guidelines.

4.6 Spills Management

For a low or medium risk MAB waste should be disposed of in accordance with clinical waste guidelines.

In the case of high risk MABs, spills are to be managed in accordance with the Safety Data Sheet provided by the manufacturer and Cytotoxic Medication Administration and Handling (see reference list for relevant facility document). If the MAB contains a cytotoxic agent then a cytotoxic spill kit is required.

This spill must be reported to local Work Health and Safety Unit who will assist with further reporting if required.

4.7 Staff Training

The relevant line manager is to ensure training is provided to workers prior conducting work with MABs. Minimum training requirements includes:

- Aware of the requirements set out in this procedure
- Training in the specific Safe Work Procedures for medium and high risk MABs
- Competency in *My Health Learning Course* Aseptic Technique (code 40027445)
- Complex dosing calculations or complex reconstitution techniques
- For workers who handle high risk and cytotoxic MABs, competency in *My Health Learning Course* Handling Antineoplastic Drugs and Related Waste Safety (code 48173057).

Additional training resources include eviQ Antineoplastic drug administration for the non-cancer setting and Antineoplastic Drug Administration Course (available through Cancer Institute NSW and requires free registration to access).

4.8 Health Monitoring

Where workers are handling and dispensing high risk MABs, the Manager will implement health monitoring as outlined in the SESLHDPR/378 - Health Monitoring - Occupational Health Exposures other than Infectious Diseases.

5. DOCUMENTATION

Workers are required to document the use of MABs as part of their standard medication documentation processes.

6. AUDIT

Clinical incidents relating to MABs will be audited based on reports within the Incident Information Management System.

7. REFERENCES

7.1 External

- Risk Management Technologies, ChemAlert (accessed 19/11/2021).
- SafeWork NSW - SW08559 Cytotoxic drugs and related risk management guide
- Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel. *Internal Medicine Journal:* 44 (2014)
- SafeWork Australia - Health Monitoring for Exposure to Hazardous Chemicals
- COSA and CPG Position Statement - Safe handling of monoclonal antibodies in healthcare settings
- M. Alexander, J. King, A. Bajel, C. Doecke, P. Fox, S. Lingaratnam, J.D. Mellor, L. Nicholson, I. Roos, T. Saunders, J. Wilkes, R. Zielinski, J. Byrne, K. MacMillan, A. Mollo, S. Kirsa and M. Green. (2014).Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel. Accessed [19/11/2021] at http://www.wcmics.org/guidelines/20140422_MABs_Guidelines.pdf
- eviQ Resource Document - Safe Handling and Waste Management of Hazardous Drugs

7.2 Internal

- SESLHDPR/378 - Health Monitoring - Occupational Health Exposures other than Infectious Diseases.
- SGH-TSH CLIN201 - Cytotoxic Medication including staff training, administration, extravasation and post administration
- SSEH CLIN052 - Cytotoxic Medication Administration and Handling
- POWH CLIN131 - Cytotoxic Medication Administration and Handling

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
September 2014	1	New procedure Author - Peter Kuszelyk Endorsed by Executive Sponsor, Sharon Litchfield
February 2015	1	Endorsed by D&QUMC on 12 February 2015
March 2015	1	Endorsed by CQC on 11 March 2015
June 2015	2	Hyperlink added to SharePoint page - http://sesinet/sites/HSW/Monoclonal/Pages/default.aspx and Appendix 1 removed
May 2018	3	Content review and update of links
June 2018	3	Endorsed by Executive Council
March 2019	4	Minor review - change to glove requirement recommendations from QUM Committee incorporated into document. Endorsed by Executive Sponsor. April 2019 - Reviewed and endorsed by Amy Minett, Lead Pharmacist, QUMC
May 2019	4	Formatted by Executive Services prior to publishing.
June 2020	5	Risk rating reduced to High Risk. Review date amended to May 2021 to align with High Risk rating. Executive Sponsor updated from Director Workforce Services to Director People and Culture. Approved by Executive Sponsor.
November 2021	6	Minor review commenced. Further detail provided regarding the general principles and risk rating for specific monoclonal antibodies (see 4. Procedure). Appendix 1 updated to reflect monoclonal antibodies available in SESLHD at time of writing. Reviewed by Graeme Wright (SESLHD Health & Safety Advisor).
February 2022	6	Approved by Executive Sponsor. Approved at Quality Use of Medicines Committee.

Appendix 1 – Monoclonal Antibody Risk Rating and Handling Precautions Guide

Monoclonal Antibody	Risk Level (Likelihood/consequence)	Potential Response	Risk Level (LDH Consensus)	Preparation Handling Precautions	Administration Handling Precautions
Belantamab mafotin*#	Dermal – likely/high Oral – unlikely/high Inhalation – possible/high Mucosal – unlikely/high	Cytotoxic drug. If used therapeutically under controlled clinical conditions, the potential for adverse health effects is minimised. Adverse health effects via occupational exposure are not anticipated, however, should over exposure occur, possible effects may be hair loss, bone marrow damage and allergic skin reactions. Refer to medical doctor/specialist for advice regarding adverse side effects.	High	**Use cytotoxic precautions**	**Use cytotoxic precautions**
Brentuximab Vedotin	Dermal – likely/high Oral – unlikely/high Inhalation – possible/high Mucosal – unlikely/high	Cytotoxic drug. If used therapeutically under controlled clinical conditions, the potential for adverse health effects is minimised. Adverse health effects via occupational exposure are not anticipated, however, should over exposure occur, possible effects may be hair loss, bone marrow damage and allergic skin reactions. Refer to medical doctor/specialist for advice regarding adverse side effects.	High	**Use cytotoxic precautions**	**Use cytotoxic precautions**
Polatuzumab vedotin*	Dermal – likely/high Oral – unlikely/high Inhalation – possible/high Mucosal – unlikely/high	Cytotoxic drug. If used therapeutically under controlled clinical conditions, the potential for adverse health effects is minimised. Adverse health effects via occupational exposure are not anticipated, however, should over exposure occur, possible effects may be hair loss, bone marrow damage and allergic skin reactions. Refer to medical doctor/specialist for advice regarding adverse side effects.	High	**Use cytotoxic precautions**	**Use cytotoxic precautions**
Sacituzumab govitecan#*	Dermal – likely/high Oral – unlikely/high Inhalation – possible/high Mucosal – unlikely/high	Cytotoxic drug. If used therapeutically under controlled clinical conditions, the potential for adverse health effects is minimised. Adverse health effects via occupational exposure are not anticipated, however, should over exposure occur, possible effects may be hair loss, bone marrow damage and allergic skin reactions. Refer to medical doctor/specialist for advice regarding adverse side effects.	High	**Use cytotoxic precautions**	**Use cytotoxic precautions**

Trastuzumab deruxtecan	Dermal – likely/high Oral – unlikely/high Inhalation – possible/high Mucosal – unlikely/high	Cytotoxic drug. If used therapeutically under controlled clinical conditions, the potential for adverse health effects is minimised. Adverse health effects via occupational exposure are not anticipated, however, should over exposure occur, possible effects may be hair loss, bone marrow damage and allergic skin reactions. Refer to medical doctor/specialist for advice regarding adverse side effects.	High	**Use cytotoxic precautions**	**Use cytotoxic precautions**
Trastuzumab emtansine	Dermal – likely/high Oral – unlikely/high Inhalation – possible/high Mucosal – unlikely/high	Cytotoxic drug. If used therapeutically under controlled clinical conditions, the potential for adverse health effects is minimised. Adverse health effects via occupational exposure are not anticipated, however, should over exposure occur, possible effects may be hair loss, bone marrow damage and allergic skin reactions. Refer to medical doctor/specialist for advice regarding adverse side effects.	High	**Use cytotoxic precautions**	**Use cytotoxic precautions**
Adalimumab*	Dermal – Likely/none Oral – Unlikely/low Inhalation – Unlikely/moderate Mucosal – Unlikely/moderate	Not determined. Produced little to no skin irritation in animals.	Moderate	Eye and face protection: wear eye protection appropriate to handing activities Hand protection: wear impervious gloves Body protection: wear coveralls if splashing or contact may occur Respiratory protection: where an inhalation risk exists, wear an approved respirator	No additional precautions
Alemtuzumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear rubber or latex gloves Body protection: no PPE specified Respiratory protection: no PPE specified	No additional precautions
Atezolizumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear PVC or rubber gloves Body protection: wear a laboratory coat Respiratory protection: where an inhalation risk exists, wear a Class P1 (Particulate) respirator	No additional precautions

Avelumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not determined, but may cause irritation and be a potential allergen.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear nitrile or latex gloves Body protection: no PPE specified Respiratory protection: no PPE specified	No additional precautions
Basiliximab*	Dermal – likely/none Oral – unlikely/low Inhalation – possible/moderate (preparation), unlikely/moderate (administration) Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not determined, but may cause irritation and be a potential allergen.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear protective gloves Body protection: wear long sleeved clothing Respiratory protection: no PPE specified	No additional precautions
Belimumab*	Dermal – likely/none Oral – unlikely/low Inhalation – possible/moderate (preparation), unlikely/moderate (administration) Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Health injuries are not known or expected under normal use.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear protective gloves Body protection: wear suitable protective clothing as protection against splashing or contamination Respiratory protection: no PPE specified	No additional precautions
Bevacizumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Skin contact may result in irritation, rash and dermatitis. Eye contact may result in irritation, lacrimation, pain and redness.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear PVC or latex gloves Body protection: wear a PVC apron and impervious coveralls Respiratory protection: where an inhalation risk exists, wear a Full-face Type A-Class P1 (Organic gases/vapours and Particulate) respirator	No additional precautions
Blinatumomab*	Dermal – likely/none Oral – unlikely/low Inhalation – possible/moderate (preparation), unlikely/moderate (administration) Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Does not meet GHS Classification Criteria and therefore is not classified.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear gloves Body protection: wear a laboratory coat or other protective garment if splashing is possible Respiratory protection: no PPE specified	No additional precautions

Cemiplimab*#	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Does not meet GHS Classification Criteria and therefore is not classified.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear protective gloves Body protection: wear impervious clothing Respiratory protection: wear a suitable respirator	No additional precautions
Cetuximab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Skin contact may result in irritation, redness, pain and rash. Eye contact may result in irritation, lacrimation, pain and redness. Cetuximab may cause sensitisation by inhalation.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear PVC or rubber gloves Body protection: when using large quantities or where heavy contamination is likely, wear coveralls Respiratory protection: no PPE specified	No additional precautions
Daratumumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Skin contact may result in irritation, redness, pain and rash. Eye contact may result in irritation, lacrimation, pain and redness.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear PVC or rubber gloves Body protection: when using large quantities or where heavy contamination is likely, wear coveralls Respiratory protection: no PPE specified	No additional precautions
Dinutuximab*#	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	There is at present no information or indication of human health or physical/chemical hazardous properties.	Moderate	Eye and face protection: wear goggles or safety glasses Hand protection: wear latex or vinyl gloves Body protection: wear a laboratory coat or apron Respiratory protection: required when vapours/aerosols are generated	No additional precautions
Durvalumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear PVC or rubber gloves Body protection: wear a laboratory coat Respiratory protection: no PPE specified	No additional precautions
Eculizumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear nitrile or latex gloves Body protection: no PPE specified Respiratory protection: no PPE specified	No additional precautions

Idarucizumab*	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	No data available.	Moderate	Eye and face protection: wear safety glasses with side-shields Hand protection: wear nitrile or rubber gloves Body protection: wear a laboratory coat or coveralls Respiratory protection: no PPE specified	No additional precautions
Infliximab	Dermal – likely/none Oral – unlikely/low Inhalation – possible/moderate (preparation), unlikely/moderate (administration) Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Skin contact may result in irritation, rash and dermatitis. Eye contact may result in irritation, lacrimation and redness. May cause an allergic skin reaction.	Moderate	Eye and face protection: wear dust-proof goggles Hand protection: wear PVC or rubber gloves Body protection: when using large quantities or where heavy contamination is likely, wear coveralls Respiratory protection: at high dust levels, wear a Class P1 (Particulate) respirator	No additional precautions
Ipilimumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Skin contact may result in irritation, redness, pain and rash. Eye contact may result in irritation, lacrimation, pain and redness.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear PVC or latex gloves Body protection: wear a PVC apron and impervious coveralls Respiratory protection: where an inhalation risk exists, wear a Full-face Type A-Class P1 (Organic gases/vapours and Particulate) respirator	No additional precautions
Mepolizumab*	Dermal – likely/none Oral – unlikely/low Inhalation – possible/moderate (preparation), unlikely/moderate (administration) Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Health injuries are not known or expected under normal use.	Moderate	Eye and face protection: wear safety glasses with side-shields Hand protection: wear protective gloves Body protection: wear a laboratory coat or coveralls Respiratory protection: no PPE specified	No additional precautions
Natalizumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear PVC or rubber gloves Body protection: wear a laboratory coat Respiratory protection: no PPE specified	No additional precautions

Nivolumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Skin contact may result in irritation, redness, pain and rash. Eye contact may result in irritation, lacrimation, pain and redness.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear PVC or latex gloves Body protection: wear a PVC apron and impervious coveralls Respiratory protection: where an inhalation risk exists, wear a Full-face Type A-Class P1 (Organic gases/vapours and Particulate) respirator	No additional precautions
Obinutuzumab*	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Does not meet GHS Classification Criteria and therefore is not classified.	Moderate	Eye and face protection: wear safety glasses with side-shields Hand protection: wear protective gloves Body protection: wear impervious clothing Respiratory protection: wear a suitable respirator	No additional precautions
Ocrelizumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear rubber or latex gloves Body protection: no PPE specified Respiratory protection: no PPE specified	No additional precautions
Ofatumumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Skin contact may result in irritation, redness, pain and rash. Eye contact may result in irritation, lacrimation, pain and redness.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear PVC or rubber gloves Body protection: when using large quantities or where heavy contamination is likely, wear coveralls Respiratory protection: no PPE specified	No additional precautions
Omalizumab*	Dermal – likely/none Oral – unlikely/low Inhalation – possible/moderate (preparation), unlikely/moderate (administration) Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	May cause allergic respiratory reactions.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear neoprene, nitrile or butyl rubber gloves Body protection: no PPE specified Respiratory protection: no PPE specified	No additional precautions
Palivizumab*	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Does not meet GHS Classification Criteria and therefore is not classified.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear impervious gloves Body protection: wear appropriate body coverings if contact may occur Respiratory protection: wear an approved respirator	No additional precautions

Panitumumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear rubber or latex gloves Body protection: no PPE specified Respiratory protection: no PPE specified	No additional precautions
Pembrolizumab	Dermal – likely/none Oral – unlikely/low Inhalation – possible/moderate (preparation), unlikely/moderate (administration) Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Skin contact may result in irritation, rash and dermatitis. Eye contact may result in irritation, lacrimation, pain and redness.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear PVC or latex gloves Body protection: wear a PVC apron and impervious coveralls Respiratory protection: where an inhalation risk exists, wear a Full-face Type A-Class P1 (Organic gases/vapours and Particulate) respirator	No additional precautions
Pertuzumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Skin contact may result in irritation, redness, pain and rash. Eye contact may result in irritation, lacrimation, pain and redness.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear PVC or rubber gloves Body protection: when using large quantities or where heavy contamination is likely, wear coveralls Respiratory protection: no PPE specified	No additional precautions
Ramucirumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear rubber or latex gloves Body protection: no PPE specified Respiratory protection: no PPE specified	No additional precautions
Ranibizumab*	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant based on available information.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear protective gloves Body protection: wear protective suit Respiratory protection: no PPE specified	No additional precautions
Ravulizumab*#	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Does not meet GHS Classification Criteria and therefore is not classified.	Moderate	Eye and face protection: wear safety glasses with side shields, splash-proof googles or full face shield. Hand protection: wear nitrile or other impervious gloves Body protection: wear a laboratory coat or other protective over garment if skin contact is likely Respiratory protection: no PPE specified	No additional precautions

Rituximab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear PVC or rubber gloves Body protection: wear a laboratory coat Respiratory protection: no PPE specified	No additional precautions
Siltuximab*	Dermal – Likely/none Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate (preparation), unlikely/moderate (administration)	Does not meet GHS Classification Criteria and therefore is not classified. It is not expected to be absorbed via the oral, dermal, or inhalation routes of exposure.	Moderate	Eye and face protection: no PPE specified Hand protection: wear gloves Body protection: no PPE specified Respiratory protection: no PPE specified	No additional precautions
Sotrovimab*	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Knowledge about health hazard is incomplete. No adverse effects due to skin contact are expected. Expected to be low ingestion hazard. May cause discomfort if swallowed. Direct contact with eyes may cause temporary irritation.	Moderate	Eye and face protection: wear safety glasses with side shields Hand protection: wear suitable chemical resistant protective gloves Body protection: wear protective clothing as protection against splashing or contamination Respiratory protection: wear a mask as protection against inhalation.	As per COVID-19 Infection Prevention and Control: Routine Care of a Suspected or Confirmed COVID-19 Patient.
Tislelizumab#*	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	No known hazardous ingredients. Direct contact with skin or eyes may cause temporary irritation.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear nitrile, neoprene or butyl rubber gloves Body protection: no PPE specified Respiratory protection: no PPE specified	No additional precautions
Tocilizumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear dust-proof goggles Hand protection: wear butyl or nitrile or neoprene or rubber or latex gloves Body protection: no PPE specified Respiratory protection: no PPE specified	No additional precautions
Trastuzumab	Dermal – Likely/none Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear dust-proof goggles Hand protection: wear butyl or nitrile or neoprene or PVC or rubber gloves Body protection: wear a laboratory coat Respiratory protection: where an inhalation risk exists, wear a Class P1 (particulate) respirator	No additional precautions

Ustekinumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear nitrile or latex gloves Body protection: no PPE specified Respiratory protection: no PPE specified	No additional precautions
Vedolizumab	Dermal – Likely/none Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate (preparation), unlikely/moderate (administration)	Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear dust-proof goggles Hand protection: wear PVC or rubber gloves Body protection: wear a laboratory coat Respiratory protection: where an inhalation risk exists, wear a Class P1 (Particulate) respirator	No additional precautions
** Medication Safety Data Sheet not published on ChemAlert* *# Medicines not registered for use in Australia*					